
REPORT TITLE

COMMENTS OF THE ENDOSULFAN TASK FORCE ON
THE REVISED OCCUPATIONAL EXPOSURE ASSESSMENT ON ENDOSULFAN EC
AND WP FORMULATION IN THE REREGISTRATION ELIGIBILITY DECISION
DOCUMENT FOR ENDOSULFAN

**(This document was prepared as a pdf file for the public docket
without Attachment B and C)**

DATA REQUIREMENT

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Statement of No Data Confidentiality Claims

No Claim of Confidentiality is made for any information contained in this report on the basis of its falling within the scope of FIFRA 10 (d)(1)(A), (B), or (C).

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Statement of Good Laboratory Practice

The following occupational exposure assessments for Endosulfan are not subject to the principles of 40 CFR Part 160, Good Laboratory Practice Standards, as promulgated in Federal Register, 54, No.158, 34067-34704, 17 August 1989. Key studies represented by the data summarized and discussed in this report may have been conducted in accordance with the appropriate GLP standards as verified by the GLP statements of the corresponding study reports.

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Date: 10/22/2001

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COMMENTS OF THE ENDOSULFAN TASK FORCE ON THE REVISED USEPA OCCUPATIONAL EXPOSURE ASSESSMENT FOR THE REREGISTRATION ELIGIBILITY DECISION DOCUMENT ON ENDOSULFAN

I. EXECUTIVE SUMMARY

A. Background

The purpose of this document is to provide comments and suggested alternative approaches to estimating worker exposures in response to the USEPA's third review of the potential human health effects of occupational exposure to endosulfan (CAS No. 115-29-7), as reflected in the revised occupational exposure assessment for the Reregistration Eligibility Decision (RED) Document on endosulfan (USEPA 2001a). These comments also present formulation-specific results of an assessment of mixer/loader/applicator and post-application occupational exposures associated with the use of endosulfan, which is the active ingredient (a.i.) in the emulsifiable concentrate (EC) and wettable powder (WP) formulations being supported by the Endosulfan Task Force (ETF).

B. Use Information

The specific example product labels assessed include Phaser[®] 3EC [USEPA Reg. No. 264-638], which is an emulsifiable concentrate formulation containing 3.0 lbs of endosulfan per gallon of formulation, Phaser[®] 50WSB [USEPA Reg. No. 264-656], which contains 50 percent active ingredient in wettable powder form in water soluble bags, and Thiodan[®] 50WP, which contains 50 percent active ingredient in wettable powder form, but is not packaged in water soluble bags [USEPA Reg. No. 279-1380]. These formulations are used to control insects in a variety of agricultural crops (including, for example, melons, peaches, apples, grapes, sweet corn, lettuce, potatoes, carrots, cauliflower, cotton, beans, strawberries, tobacco, tomatoes), commercially-grown trees and shrubs, and commercially-grown greenhouse tomatoes.

C. Toxicology and Endpoint Selection

The specific position of the Endosulfan Task Force with respect to toxicology issues has been provided as part of a separate 30-day response to the Agency's proposed risk assessment for the Reregistration Eligibility Decision (RED) document on endosulfan (Aventis 2000; ETF 2000a; ETF 2001a). Appropriate toxicological benchmarks were identified for the dermal, oral, and inhalation routes. A total of 5 subchronic studies in rats are available to assess the potential dermal toxicity of endosulfan. Two 21-day dermal toxicity studies in rats have been conducted in accordance with USEPA guidelines [MRID Nos. 00146841 and 00147744]. One non-guideline study is available in the scientific literature (Dikshith et al. 1988). In addition, there are two 21-day dermal toxicity studies with endosulfan WP or EC as the test materials [MRID Nos. 41048506 and 41048505,

respectively]. Based on the entire weight of evidence, it was determined by the ETF that the most appropriate value for assessing the risk associated with short-term and intermediate-term dermal exposures is the dermal NOAEL of 12 mg/kg/day. The justification for selection of 12 mg/kg/day as the dermal NOEL has been presented separately in prior submissions to the Agency (ETF 2000a; ETF 2001a). Therefore, the toxicological benchmark used by the ETF for assessment for short-term dermal exposures for handlers, and for assessment of short-term and intermediate-term dermal exposures to workers during reentry of treated fields is the NOAEL of 12 mg/kg/day.

With regard to the inhalation route, Ross et al. (2001) have noted the often high toxicity of fine pesticide particles that are produced artificially in the laboratory when compared to field situations where predominantly non-respirable aerosols are produced by field application equipment. Concern for inhalation exposures is further mitigated by label statements for endosulfan products that require the use of organic vapor-removing respirators with appropriate approved pre-filters. Furthermore, Pependorf et al. (1982) has shown that respirable pesticide-containing particles on treated foliage surfaces makes up only a small percentage of the total deposited amount, and would contribute only a small fraction of total dose if resuspended during worker reentry activities. Thus, inhaled doses during handling of endosulfan (mixing/loading, application, flagging) and during post-application work activities in treated fields are anticipated to be minimal.

It is the position of the ETF that the use of the inhalation NOAEL in assessing worker risk via the inhalation route is over-restrictive, and grossly overestimates doses to the deep lung from use of endosulfan formulations. The great majority of particles that may bypass the respirator due to variability in fit will be of sufficiently large diameter to impact the upper respiratory tract, leading to clearance and swallowing of the material, thus, resulting in an oral dose. Accordingly, the ETF proposes the use of the NOEL of 1.5 mg/kg/day from the oral acute neurotoxicity study in rats [MRID No. 44403101] for assessing the worker risk from endosulfan formulations.

D. Assessment of Handler Exposures to Endosulfan

(1) Handler Scenarios. The following handler exposure scenarios were identified for endosulfan according to the USEPA work activity code: (1a) mixing/loading of liquid formulations for aerial application; (1b) mixing/loading of liquid formulations for chemigation; (1c) mixing/loading of liquid formulations for groundboom application; (1d) mixing/loading of liquid formulations for airblast application; (1f) mixing and loading liquid formulations for plant and root dip; (2a) mixing/loading of wettable powder formulations for aerial application; (2b) mixing/loading of wettable powder formulations for groundboom application; (2c) mixing/loading of wettable powder formulations for airblast application; (2e) mixing/loading of wettable powder formulations for plant and root dip; (3) aerial application of liquid sprays; (4) groundboom application of liquid sprays; (5) airblast application of liquid sprays; (7) applying dip treatment to roots or whole plants; (11) mixing/loading/applying liquids with a backpack sprayer; and (12) flagging of aerial spray applications. Exposure scenarios related to rights-of-way applications, low-pressure hand wand, and high-pressure hand wand were not assessed because these use patterns are not supported by ETF labels for endosulfan.

(2) *Surrogate occupational exposure data.* The primary source of surrogate worker exposure data for estimation of mixer/loader, applicator, and flagger exposures as the Pesticide Handlers Exposure Database (PHED), Version 1.1. This database, which contains exposure monitoring data and other ancillary data for over 1,700 worker replicates, was used to develop exposure estimates for each handler scenario (normalized by lb a.i. handled) for the inhalation route, hand, and “other” dermal areas. The PHED data used were from the PHED surrogate guide (USEPA 1998a) for a single layer of clothing (i.e., long pants, long sleeve-shirt). PHED data for “other” dermal exposures were adjusted to reflect the anticipated reduction in exposures for body parts covered by coveralls, (i.e., chest, back, lower arms, forearms, thighs and lower legs). Protection factors were also applied, where appropriate, to reflect the use of chemical-resistant gloves, respirator and protective headgear for overhead exposures. The protection factors used in the assessment include a 50 percent protection for body parts covered by coveralls, 10-fold reduction in hand exposures when chemical-resistant gloves are used, 10-fold reduction in inhalation exposures when an organic-vapor cartridge/canister respirator is used with an approved pre-filter, and a 50 percent reduction in exposures for the use of protective headgear. It is the position of the ETF that these protection factors are realistic, and likely conservative, and are supported by data in the literature. Exposures were not calculated for the USEPA “baseline” exposure scenarios because these scenarios provide less clothing and PPE than what is required by the example product labels.

(3) *Estimation of handler exposures and risks.* Handler exposures to endosulfan were estimated using the PPE-adjusted normalized exposure data from PHED, crop-specific maximum label application rates, and typical assumptions on the number of acres treated per work day. Route-specific risks associated with handler exposures were expressed as the Margins-of-Exposure (MOEs). Handler exposures to endosulfan are anticipated to be short-term in nature (i.e., less than 30 days); therefore, comparison of exposures to short-term toxicity benchmarks is appropriate. The MOE is calculated by dividing the relevant NOAEL (12 mg/kg/day for the dermal route and 1.5 mg/kg/day for assessing the risk of inhalation exposures) by the route-specific exposure. The target MOE is 100, which is in agreement with the Agency’s selected MOE target for handler exposures. The calculated dermal and inhalation MOEs are greater than 100 without additional PPE or engineering controls for the great majority of handler exposure scenarios. Exceptions are as follows:

- The MOEs associated with dermal and inhalation exposures are less than 100 for open mixing/loading of wettable powder formulations (without water soluble packets) for aerial application;
- The MOEs associated with dermal exposures are less than 100 for open mixing/loading of wettable powder formulations (without water soluble packets) for groundboom application and airblast application (except ornamentals);
- The MOEs associated with dermal exposures are less than 100 for open mixing/loading of liquid formulations for aerial application to pecans and cotton;

- The MOEs associated with dermal exposures are less than 100 for airblast application of sprays (except ornamentals).

Acceptable MOEs associated with handler exposures are predicted for open mixing/loading of wettable powder formulations when water-soluble packets are used, and for airblast application when an enclosed cab is used.

E. Assessment of Post-Application Occupational Exposures to Endosulfan

(1) *Dislodgeable foliar residue data.* This assessment is based on dislodgeable foliar residue (DFR) data on Phaser[®] 3EC and Phaser[®] 50WSB from studies conducted on behalf of the Endosulfan Task Force (ETF) on melons, peaches, and grapes (AgrEvo 1997) [MRID No.444031-02]. This same DFR study was used by the Agency in the revised HED occupational exposure assessment (USEPA 2001a). When the DFR data are forced to fit a single log-linear regression across the entire time frame of the DFR data, mediocre correlation coefficients occur (e.g., 0.71 for peaches, 0.52 for grapes, and 0.76 for melons for the EC formulation). If the DFR data are plotted in a log-linear fashion (i.e., \ln [DFR] vs. time), the biphasic nature of the dissipation curve is readily apparent. For endosulfan, there appears to be an initial rapid decline phase (“Phase 1”) followed by a much slower decline phase (“Phase 2”). Thus, if the data for the EC or WP formulation from the study report are plotted in a log-linear form, the DFR data suggest a “hockey stick” type of plot rather than a single straight line plot. The half-lives estimated for the 2 phases for a given crop/formulation type combination are dramatically different, as shown in Table 1. The break points between the 2 phases appear to be just after Day 7 post-application for the EC formulation and just after Day 10 post-application for the WP formulation. Separate regression equations for the two phases were used to calculate predicted DFR for each day post-application.

Table 1. Half-Life Estimates Based on Biphasic (2-Compartment) Kinetics (Agrevo 1997)

Formulation Type	Crop	Foliar Dissipation Half-Life (Days)	
		Rapid-Phase (Phase 1)	Slow-Phase (Phase 2)
EC	Melons	0.7	8.6
	Peaches	0.4	10.5
	Grapes	0.7	11.1
WP	Melons	2.9	2,240
	Peaches	0.3	6.2
	Grapes	2.5	84.8

(2) Estimation of short-term post-application worker exposures and risks. Short-term daily exposures were calculated to allow comparison to the daily exposures estimated by the Agency. The worker post-application occupational assessment provided in this report was conducted using the “high-end” transfer coefficients from the Agricultural Reentry Task Force (ARTF) efforts, as summarized in the USEPA HED Policy Memo 3.1 (USEPA 2000a). Daily DFR levels predicted by regression equations based on biphasic kinetics were used in calculating exposures. To calculate the crop-specific post-application worker exposures, the DFR data were adjusted to reflect the crop-specific application rates. MOEs were calculated using the estimated exposures and the dermal NOAEL of 12 mg/kg/day. The results of the short-term worker reentry risk assessment can be summarized in terms of the post-application day at which the MOE first equals or exceeds the target MOE of 100. For the emulsifiable concentrate (EC) formulation, the calculated MOE equals or exceeds the target MOE of 100 on Day 0 or Day 1 for 21 of the 41 crop/work activity combinations. For the EC formulation, 5 of the 41 crop/work activity combinations are associated with an REI of 2 days, 8 of the 41 crop/work activity combinations are associated with an REI of 3 days, 4 are associated with an REI of 4 days, and 3 are associated with an REI greater than or equal to 5 days. For the wettable powder (WP) formulation, the calculated MOE equals or exceeds the target MOE of 100 on Day 0 or Day 1 for 12 of the 41 crop/work activity combinations. For the WP formulation, 6 of the 41 crop/work activity combinations are associated with an REI of 2 days, none of the 40 crop/work activity combinations is associated with an REI of 3 days, and 4 are associated with an REI of 4 days. Nineteen of the crop/work activity combinations are associated with an REI greater than or equal to 5 days. Seven of the crop/work activity combinations for the WP formulation are associated with an REI greater than 1 week (7 days), including selected activities for table grapes, juice and raisin grapes, apples, apricots, cherry, plum, peach, nectarine, pear, prune, brussel sprouts, cauliflower, blueberries, broccoli, cabbage, and sweet corn. (See Table 20 for a more detailed summary of short-term occupational post-application exposures and REIs, respectively).

(3) Estimation of intermediate-term post-application worker exposure and risks. Because endosulfan is registered for a large number of crops, sometimes involving multiple applications, there is potential for post-application workers to receive repeated exposures to endosulfan during the reentry of treated growing areas to conduct various work activities. The anticipated duration of intermediate-term exposures may range from 30 days to several months. Because it is anticipated that workers will travel from field to field for work, it is unlikely that any given worker will encounter the same foliar residue every day. A reasonable yet conservative approach taken was to assume that the worker comes into contact with the average of residue values that occurs within 30 days after the target MOE is attained. For evaluation of intermediate-term post-application occupational risks, it is the position of the ETF that the most appropriate target MOE for assessing intermediate-term post-application occupational exposures to endosulfan is 100. The assumptions used in estimating intermediate-term exposures included: (1) the “high-end” transfer coefficients for each crop category per USEPA HED Policy Memo No. 3.1 (USEPA 2000a), which is based on the ARTF database; (2) the 30-day post-REI average DFR based on biphasic regression equations, adjusted for crop-specific use rates; (3) national average crop-specific application rates (or maximum label rates when an average is not available; (4) an exposure duration of 8 hours per day; (5) an average body weight of 70 kg; and (6) a dermal NOAEL of 12 mg/kg/day.

As must be the case, all of the crop/work activity for both the WP and EC formulations, all of the intermediate-term occupational post-application exposures to endosulfan are associated with the ETF target MOEs of 100 or greater. Furthermore, for the EC formulation, all of the intermediate-term post-application exposures are associated with MOEs that equal or exceed the Agency's target MOE of 300. For the WP formulations, the only intermediate-term post-application exposures that exceed the Agency's target MOE of 300 are (1) cane turning, tying, and girdling of table grapes (MOE = 200); (2) tying, training, hand harvesting, hand pruning, and thinning of juice grapes (MOE = 170); (3) thinning, staking, topping, training, and hand harvesting of cherries, pears, and plums/prunes (280); and (4) detasseling of sweet corn (MOE = 280). (See Table 21 for a summary of intermediate-term post-application occupational exposures and associated MOEs).

II. INTRODUCTION

A. Purpose

This document provides an alternative assessment of formulation-specific mixer/loader, applicator, flagger, and worker reentry exposures associated with the use of endosulfan (CAS No. 115-29-7). This is being submitted in response to the USEPA's third review of the potential human health effects of occupational exposure to endosulfan, as reflected in the revised HED occupational exposure assessment (USEPA 2001a). Endosulfan [6,7,8,9,10-hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3-oxide] (CAS No. 115-29-7) is the active ingredient (a.i.) in the emulsifiable concentrate (EC) and wettable powder (WP) formulations being supported by the Endosulfan Task Force (ETF). The example product labels are for Phaser® 3EC [USEPA Reg. No. 264-638], which is an emulsifiable concentrate formulation containing 3.0 lbs of endosulfan per gallon of formulation, Phaser® 50WSB [USEPA Reg. No. 264-656], which contains 50 percent active ingredient in wettable powder form in water soluble bags, and Thiodan® 50WP, which contains 50 percent active ingredient in wettable powder form (not packaged in water soluble bags).

Endosulfan formulations supported by the ETF are used to control insects in a variety of agricultural crops (including, for example, peaches, apples, melons, grapes, sweet corn, lettuce, potatoes, cauliflower, carrots, cotton, beans, strawberries, tobacco, tomatoes), commercially-grown trees and shrubs, and commercially-grown greenhouse tomatoes. Alternative mixer/loader/applicator and flagger exposure estimates and alternative short-term and intermediate-term exposures estimates and MOEs associated with worker reentry into treated fields following application are provided in tabular form for direct comparison to the estimates developed by the Agency.

B. Criteria for Conducting Exposure Assessments

The ETF agrees with the Agency that an occupational exposure assessment is required for endosulfan because of (1) the available toxicological data on endosulfan and (2) the likelihood of exposures to handlers of the EC, WSB, and WP formulations (i.e., mixer/loader/applicators and flaggers) and to persons entering treated sites after application is complete. The assumptions used in this re-assessment of handler and reentry exposures to endosulfan, in comparison to the assumptions used in the revised HED exposure assessment document (USEPA 2001a) are noted in Table 2. Several of the crop-specific use rates employed in the revised HED document are inconsistent with the maximum label rates of products supported by the ETF, as indicated in this assessment. ETF believes that less conservative protection factors could be used in assessing handler exposures than used in the revised HED occupational assessment (USEPA 2001a). However, the assumptions for the handler portion of this assessment have largely been harmonized with the assumptions of the Agency, with a few exceptions as noted in Table 2.

The post-application occupational assessment relies on dislodgeable foliar residue (DFR) data on endosulfan from studies conducted by member companies of the Endosulfan Task Force (ETF) on melons, peaches, and grapes. While these data were provided to the Agency and have been used by the Agency in development of the revised RED document, the ETF takes a distinctly different interpretation of these data. Because statistical evaluation presented in this assessment demonstrates that biphasic kinetics more readily describe the DFR dissipation curves than the simple log-linear approach taken by the Agency in its latest revision of the worker exposure assessment (USEPA 2001a), the ETF believes that it is important for the Agency to reconsider its position on the form of the dissipation curves. In calculating short-term and intermediate-term post-application occupational exposures, the Agency has used “high-end” transfer coefficient (TC) values from the Agricultural Reentry Task Force (ARTF) that differ somewhat from central-tendency crop-specific/task-specific ARTF TC values. However, we have adopted the TC values from the revised HED document (USEPA 2001a) in our re-assessment provided here. The ETF reserves the right to re-consider whether central tendency TC estimates might provide a more appropriate measure of intermediate-term post-application occupational exposures, in particular.

Table 2. Comparison of Assumptions: Revised USEPA Occupational Assessment (USEPA 2001a) and Current ETF Re-Assessment

Parameter Category	Parameter	USEPA Value	ETF Value	Comments
NOAELs	Dermal NOAEL	3.0 mg/kg/day	12 mg/kg/day	For assessing risk associated with short-term and intermediate-term worker exposures.
	Inhalation NOAEL	0.2 mg/kg/day	-----	Inhalation NOAEL not applicable to non-respirable size particles/aerosols.
	Oral NOAEL	-----	1.5 mg/kg/day (acute neurotoxicity)	An oral NOAEL is most appropriate for assessing inhalation exposures because the large particle sizes will be cleared from the upper respiratory tract and swallowed, thus becoming an oral dose.
Safety Factors	Interspecies	10x	10x	For assessing dermal and inhalation exposure risk.
	Intraspecies	10x	10x	For assessing dermal and inhalation exposure risk.
	FQPA	3x	----	Appropriately, the Agency did not use the 3x FQPA Safety Factor in assessing short-term worker risk; however the Agency's application of the 3x FQPA Safety Factor to intermediate-term worker exposures is not appropriate in the case of endosulfan.
Absorption Factors	Dermal Absorption	45 percent	Not used in calculations	
	Inhalation Absorption	100 percent	Not used in calculations	Oral NOAEL used to assess inhalation exposures.
Dissipation Curve	Form of Curve ln (DFR) vs. time	Linear	Biphasic	Biphasic kinetics better represent the data and provide higher r^2 values for the critical Phase I time period (which encompasses most of the REIs) than a linear assumption.
Transfer Coefficients	Source of TC Values	ARTF "High-End"	ARTF "High-End"	Central-tendency TC values may result in more appropriate estimates for intermediate-term post-application occupational exposures.
Protection Factors	Protective Clothing	50 percent	50 percent	Protective clothing such as coveralls.
	OV Respirator	90 percent	90 percent	OV= organic vapor removing respirator with approved pre-filter.
	Protective Gloves	90 percent	90 percent	
	Protective Headgear	None	50 percent	ETF believes that a 50 percent protection factor is a reasonable default for protective headgear.
Acres Treated/Day	Small Grains	1,200 A/day	600 A/day	600 A/day based on current California defaults; 1,200 A/day is overly conservative.
	Ornamentals	40 A/day	10 A/day	Due to the small size of ornamental operations, 40 acres/day is not realistic.

III. GENERAL COMMENTS ON THE REVISED ENDOSULFAN RED

A. *The claim that endosulfan is likely to bioaccumulate is incorrect and inconsistent with other statements made by the Agency.*

The USEPA's Endpoint Selection document (USEPA 2000b) states that "There is sufficient evidence to believe that endosulfan bioaccumulates with repeated exposure..." (p. 10). EPA's conclusion was based in part on the structural similarities of endosulfan to other polychlorinated cyclodienes such as aldrin, dieldrin, and chlordane. There is substantial data, however, to show that endosulfan is distinctly different in its potential to bioconcentrate or bioaccumulate in comparison to other polychlorinated cyclodienes (ATSDR 1993; WHO 1984; Navqvi and Vaishnavi 1993). Toxicokinetic data, with single and repeat dosing, show that following either oral or dermal exposure, endosulfan levels in tissues will plateau within 2 to 21 days, depending on the exposure route. Once steady state is reached, endosulfan is completely and rapidly metabolized and excreted (MRID Nos. 40223601, 41048504, 05003703, and 44843702; Needham and Giulianotti 1997; Needham and Giulianotti 1998; Needham, Creedy and Hemmings 1998). Furthermore, the NOAEL from the subchronic feeding study in rats (MRID No. 00145668) of 0.5 mg/kg/day and the NOAEL from the two-year chronic study in rats of 0.6 mg/kg/day are essentially identical, as are the LOAELs of 1.5 and 2.9 mg/kg/day, respectively. While both LOAELs correspond to changes in the kidneys, there is no clear progressive or incremental injury identified. Effects reported in the subchronic studies were limited to physiological adaptive changes, while the effect noted in the chronic study was associated with a slight increase in a commonly occurring lesion in aging rats. Therefore, based on the available data, there is no evidence provided in any of the studies evaluated to support EPA's suggestion that endosulfan bioaccumulates or that longer-term exposure would result in cumulative effects.

B. *The "baseline" occupational use scenarios that involve mixing/loading activities are inconsistent with endosulfan product labels and with the USEPA's Worker Protection Standards.*

The revised occupational exposure and risk assessment for the RED document (p. 31) notes that "...The baseline clothing/PPE outfit for occupational exposure scenarios is generally an individual wearing long pants, a long-sleeve shirt, no chemically-resistant gloves and no respiratory protection..." Applying this baseline clothing/PPE to occupational exposure scenarios involving mixing/loading activities is inconsistent with the USEPA's Worker Protection Standards, which require the use of chemical-resistant gloves for all mixing/loading activities. Because the hands are generally the body part that receives the highest exposures during the mixing and loading work task, total dermal exposures estimated under these conditions would far exceed those estimated under more appropriate work practices involving the mandated use of chemical-resistant gloves. Furthermore, the "baseline" occupational exposure scenarios are inconsistent with label statements for endosulfan formulations, which require considerably more clothing and protective equipment (e.g., coveralls over long-sleeve shirt and long pants, chemical-resistant gloves, organic-vapor removing respirator, protective headgear, protective boots) than represented in the "baseline"

scenario. The baseline occupational scenarios are misleading and may cause some readers to mistakenly conclude that the anticipated conditions of use will lead to unacceptable Margins of Exposure (MOEs). Therefore, the “baseline” scenario should be dropped from the assessment.

C. *Many of the mixer/loader, applicator, or mixer/loader/applicator scenarios presented in the revised RED occupational assessment chapter are not supported as label uses by the Endosulfan Task Force.*

A number of handler exposure scenarios that were assessed in the revised occupational exposure chapter by the Agency (USEPA 2001a) represent uses that are *not* supported by ETF labels for endosulfan. These unsupported uses include USEPA scenarios (1e) mixing/ loading of liquid formulations for rights-of-way application; (2d) mixing/loading of wettable powder formulations for rights-of-way applications; (6) rights-of-way applications; (8) mixing/loading and application of liquid formulations with a low-pressure hand wand; (9) mixing/loading and application of wettable powder formulations with a low-pressure hand wand; and (10) mixing/ loading/application of liquid formulations with a high-pressure hand wand. These uses should be deleted from the final RED document, because they are not relevant to product use/labels for endosulfan products manufactured or distributed by Task Force member companies.

D. *Protection factors assumed by the Agency are in some cases overly-conservative and have led to overestimation of dermal exposures by the Agency.*

Due to lack of data under clothing, the USEPA/HED often calculates dermal exposures for workers using generic protection factors (PFs) that are applied to represent various risk mitigation options, such as the use of personal protective equipment (PPE) and engineering controls including closed cab applications. The USEPA assumed that only a 50 percent PF (i.e., 50 percent reduction in exposures to the skin) is provided by normal clothing (USEPA 2001a). Assumption of a 50 percent PF for even a single layer of clothing is conservative and will likely overstate exposures. This approach is in conflict with the standard assumptions used by the California Department of Pesticide Regulation (DPR), whereby a 90 percent reduction in exposure (i.e., 10-fold protection factor) is assumed to be provided by each layer of clothing based on actual field data on the penetration of various pesticides through various types of clothing (Thongsinthusak et al, 1991a; 1991b; DPR 1995). We encourage the Agency to adopt a more reasonable and realistic science-based approach to selection of protection factors, such as those used by the California DPR.

E. *The use of a 3-fold factor to account for lack of a long-term study is not appropriate, and should be dropped from the assessment.*

There is no evidence from the available data that endosulfan would be expected to bioconcentrate in workers following an intermediate or long-term exposure period. Nor is there any evidence to support EPA’s supposition that longer-term dermal exposure would result in increased toxicity. Dermal absorption studies with endosulfan clearly show that endosulfan is absorbed very slowly through the skin, and once the skin is penetrated and a steady-state is attained, metabolism

and excretion are rapid and complete. Repeated dermal exposures longer than 30 days would result in a plateau of residues in the body within 2 to 21 days, and any cessation of exposure would result in significant reductions in body burden. Whether exposure is intermediate or long-term, data show that the 30-day dermal toxicity studies are adequate for assessment of risk to workers, and that no additional uncertainty factor is required. In Table 2 of the revised HED occupational risk assessment (USEPA 2001a), a 3x FQPA Safety Factor is mistakenly indicated for short-term dermal and short-term inhalation risk assessment. The actual short-term handler and short-term post-application occupational assessment conducted by the Agency did not use the 3x factor, as the target MOE was explicitly stated as 100 by the Agency in the revised occupational assessment (USEPA 2001a).

F. *In the case of endosulfan, it is actually more appropriate to use the NOEL from the oral study for assessing worker inhalation risks than the NOEL from the inhalation study.*

The Endpoint Selection document (USEPA 2000b) recommends the use of a 21-day inhalation study in rats (MRID No. 00147183) as the basis for the NOEL selected by the Agency for conducting short-term and intermediate-term assessments. The Agency selected a rather restrictive NOEL of 0.2 mg/kg/day from the study. The low concentration (0.0024 mg/l) and high concentration (0.0065 mg/l) groups received airborne particles that were primarily below 6 µm in diameter (MRID No. 00147183). Roughly 92 to 98 percent of the particles were below 6 µm in diameter in the case of the low concentration group and approximately 88 to 90 percent of the particles delivered to the test animals in the high concentration group were less than 6 µm in diameter. The results of this study may not be directly applicable to assessing the risk associated with worker exposures because workers are exposed primarily to a size range of larger diameter particles in the field due to use of standard application equipment. By comparison, standard agricultural spray equipment, such as airblast, groundboom and aerial spray rigs, generate relatively coarse aerosol sizes. More than 90 percent of the mass of particulates generated by agricultural application equipment are greater than 30µm in diameter (Ross et al. 2001). Thus, no more than 10 percent of the total applied mass consists of aerosols would be in the respirable range (i.e., less than 10µm in diameter). Most of the aerosols contacting the breathing zone of the applicator would be removed by the specified respirator with an approved pre-filter that is required for all mixer/loaders and applicators of endosulfan WP and EC formulations where an enclosed cab is not involved. Particles of these larger diameters generated in the field that could possibly by-pass the respirator (e.g., in cases where less than ideal fit is obtained) would be expected to become inhaled and impacted in the upper respiratory tract, after which they would be rapidly cleared and swallowed, thus, becoming an oral dose. For this reason, Ross et al. (2001) recommends that in assessing pesticide handler inhalation risk, the inhalation exposure estimate should be compared to an oral NOAEL (Ross et al. 2001). For this reason, it seems to be more appropriate to use the NOAEL of 1.5 mg/kg/day from the acute oral neurotoxicity study (MRID No. 44403101) for assessing short-term inhalation exposures to handlers (i.e., mixer/loaders, applicators, flaggers). Thus, in our re-assessment of handler exposures, the short-term oral NOAEL of 1.5 mg/kg/day is used in assessing the risk associated with short-term inhalation exposures (see Section VI).

G. *The Agency's assumption of linear dissipation kinetics does not adequately account for the data.*

In the revised occupational assessment and RED documents (USEPA, 2001b, 2001c), the Agency reverts back to its position that linear kinetics adequately describe the dissipation of endosulfan on the foliage of treated plants. This is counter to the assessment that was previously submitted by the Task Force (ETF 2000b), that clearly demonstrates the biphasic nature of the dissipation data from a study conducted on melons, peaches and grapes with the EC and WP formulations. The Agency's suggestion that linear kinetics are "good enough" is not correct. Use of biphasic kinetics leads to substantially improved correlation coefficients over the critical time period over which most of the crop-specific REIs occurs (see Table 3). For biphasic kinetics, the REI usually occurs during the first phase, or Phase I. Table 3 presents the comparison of r^2 values for linear versus biphasic kinetics assumptions.

Table 3. Dissipation of Dislodgeable Foliar Residues (DFR) of Endosulfan on Treated Crops: Comparison of r^2 Values for Linear Versus Biphasic Kinetics (ln[DFR] vs. Time)

Formulation Type	Crop	r^2 for Regression Curve Assumed for Dissipation of DFRs ^a		Comments
		Linear	Biphasic ^b	
EC	Melons	0.7608	0.9271	Biphasic r^2 value is 22 percent higher
	Peaches	0.7077	0.8869	Biphasic r^2 value is 25 percent higher
	Grapes	0.6205	0.9502	Biphasic r^2 value is 53 percent higher
WP	Melons	0.8838	0.9685	Biphasic r^2 value is 10 percent higher
	Peaches	0.9250	0.9366	Biphasic r^2 value is 1.3 percent higher
	Grapes	0.7390	0.8801	Biphasic r^2 value is 19 percent higher

^a r^2 values are rounded to 4 significant figures, based on data from Agrevo (1997) [MRID No. 0444031-02].

^b For Phase I portion of dissipation curve.

An analysis of the biphasic kinetics for the 2 formulations clearly indicates a breakpoint between Phase I and Phase II of the dissipation curves just after Day 7 for the EC formulation, and just after Day 10 for the WP formulation. While these differences in the r^2 values may seem minor, especially for the WP formulation, they have huge impacts on the calculated half-lives, as shown in Table 4. Assumption of a linear model for decline of ln (DFR) results in serious overestimation of half-life for endosulfan. For the EC formulation, assumption of a linear model results in an 8-fold overestimation of half-life for melons, a 19-fold overestimation for peaches, and a 9-fold overestimation for grapes. In the case of the WP formulation, assumption of linear dissipation kinetics results in a 2-fold overestimation of half-life for melons, 24-fold overestimation for half-life for peaches, and a 4-fold overestimation of half-life for grapes, compared to the biphasic model. The biphasic model for dissipation is a more appropriate model for dissipation than the linear

assumption used by the Agency because of the better “goodness of fit” and more accurate description of what the data are saying with the biphasic model.

Table 4. Half-Life Estimates Based on Linear Versus Biphasic (2-Compartment) Kinetics (Agrevo 1997)

Formulation Type	Crop	Foliar Dissipation Half-Life (Days)	
		Linear	Biphasic (Phase 1)
EC	Melons	5.6	0.7
	Peaches	7.6	0.4
	Grapes	6.5	0.7
WP	Melons	5.0	2.9
	Peaches	7.1	0.3
	Grapes	9.7	2.5

IV. TOXICOLOGY AND ENDPOINT SELECTION

The basis for the toxicological benchmarks and other factors used in our alternative occupational exposure assessment are shown below in Table 5. The toxicological benchmark used in this assessment of short-term and intermediate-term dermal exposures to workers was based on a series of dermal toxicity studies in rats, from which the most appropriate NOAEL of 12 mg/kg/day was identified by the Task Force. The justification for selection of 12 mg/kg/day as the dermal NOAEL has been presented separately in a prior submission to the Agency (ETF 2000a). Because label statements require the use of organic vapor-removing respirators, inhalation exposures are anticipated to be minimal. Therefore, the use of the inhalation NOAEL is thought to be over-restrictive by the ETF. Any coarse particles that may bypass the respirator if fit improperly will be of sufficiently large diameter to impact the upper respiratory tract, leading to clearance and swallowing of the material, thus, resulting in an oral dose (see below). The ETF is proposing the use of the NOAEL of 1.5 mg/kg/day from the acute neurotoxicity study in rats [MRID No. 44403101] for assessing the impact of short-term worker inhalation exposures to endosulfan formulations. Summaries of the key toxicological studies are provided below.

A. Subchronic Dermal Toxicity Studies in Rats

Five subchronic studies in rats are available to assess the potential dermal toxicity of endosulfan. Two 21-day dermal toxicity studies in rats have been conducted in accordance with USEPA guidelines [MRID Nos. 00146841 and 00147744]. One non-guideline study is available in the scientific literature (Dikshith et al. 1988). In addition, there are two 21-day dermal toxicity studies with endosulfan WP or EC as the test materials [MRID Nos. 41048506 and 41048505, respectively]. While these studies with formulated products cannot be quantitatively compared to the results from the guideline studies with technical material, they provide overall support for selection of a dermal NOAEL. Based on consistency of effects across these studies, the ETF believes that the most appropriate value for the dermal NOAEL is 12 mg/kg/day. The rationale for selection of this NOAEL is provided in Task Force submissions to the Agency (ETF 2000a; ETF 2001a).

The Agency has selected a dermal NOAEL from a 21-day dermal study using technical material (MRID No. 00146841). While the ETF concurs with the Agency's use of the dermal study, the ETF does not agree with the assessment of the NOAEL from this study. A review of the study clearly shows that the two male deaths were due to pre-existing, non-treatment-related developmental deficiencies. Furthermore, no mortalities were observed in male rats at the next highest dose of 27 mg/kg/day, and in the other four studies the lowest dose to cause mortality in males was 81 mg/kg/day. A thorough review of the study also revealed that the liver histopathological findings were considered "very slight" by the pathologist, were observed in only a few individual animals, and were neither gender-related or dose-related. Thus, the ETF believes that the most appropriate NOAEL from the dermal studies is 12 mg/kg/day, based on increased mortality in the females at 27 mg/kg/day.

B. Acute Neurotoxicity Study in Rats

In an acute neurotoxicity study [MRID No. 44403101], rats received an oral dose via gavage of endosulfan technical (98.6 percent purity). The male rats received single doses of 0, 6.25, 12.5, 25, 50, or 100 mg/kg, and female rats received single doses of 0, 0.75, 1.5, 3, 6, or 12 mg/kg. Clinical signs in the two highest dose groups (50 and 100 mg/kg for males, and 6 and 12 mg/kg for females) within 8 hours after dosing on Day 1 included tonic clonic convulsions, decreased spontaneous activities, stilted gait, stupor, prone position, squatting posture, straddled hindlimbs, bristle coat, palpebral fissure narrowing, irregular respiration and panting. Some of these effects were also observed in male rats at 25 mg/kg (LOAEL for males) and in female rats at 3 mg/kg (the LOAEL for females). The NOAEL for acute neurotoxicity was established as 1.5 mg/kg in the USEPA Endpoint Selection Document (USEPA 2000b), based on the observation of an increased incidence of convulsions within 8 hours after dosing female rats at 3 mg/kg. It is the position of the ETF that this NOAEL is the most appropriate NOAEL for assessment of short-term inhalation exposures.

Table 5. Endpoints for Assessing Occupational Risks for Endosulfan

Route/Duration	NOEL (mg/kg/day)	Effect	Study	Uncertainty Factors and Safety Factors
Short-term dermal (1 to 30 days)	12.0	Increased mortality in female rats at 27 mg/kg/day ^a	21-day dermal toxicity in rats	Interspecies: 10x Intraspecies: 10x FQPA Factor: Not relevant ^c
Intermediate-term dermal (30 days to several months) ^b	12.0	Increased mortality in female rats at 27 mg/kg/day ^a	21-day dermal toxicity in rats	Interspecies: 10x Intraspecies: 10x FQPA Factor: Not relevant ^d
Short-term inhalation (1 to 30 days)	1.5	Increased incidence of convulsions within 8 hours of dosing female rats at 3 mg/kg	Acute oral neurotoxicity study in rats ^e	Interspecies: 10x Intraspecies: 10x FQPA Factor: Not relevant ^c

^a See ETF (2000a; 2001a) for full discussion of rationale for dermal NOAEL of 12 mg/kg/day.

^b Long-term exposures concerns for workers are not relevant (see Section III).

^c The Agency has acknowledged that the 3x FQPA Safety Factor is not relevant to assessment of short-term worker risk (USEPA 2001b); the Agency has used the 3x FQPA Safety Factor only in assessing the risk associated with intermediate-term (30 to 60 day) worker exposures in the revised occupational exposure assessment (USEPA 2001a).

^d Extrapolation from 21-day study to the 30 to 60 day time-frame for workers does not justify the 3-fold FQPA Safety Factor suggested by the Agency (see Section III).

^e The acute oral neurotoxicity study in rats provides an appropriate NOAEL for evaluation of short-term inhalation exposures because most of the inhaled dose will consist of coarse aerosols that will likely be cleared from the upper respiratory tract and swallowed, thus, becoming an oral dose (see Section III).

V. DESCRIPTION OF LABELS AND PRODUCT USE

The proposed product labels are for Phaser® 3EC [USEPA Reg. No. 264-638], which is an emulsifiable concentrate formulations containing 3.0 lbs of endosulfan per gallon of formulation, Phaser® 50WSB [USEPA Reg. No. 264-656], which contains 50 percent active ingredient in wettable powder form in water soluble bags, and Thiodan® 50WP [USEPA Reg. No. 279-1380], which contains 50 percent active ingredient in wettable powder form, not packaged in water soluble bags. These formulations are used to control insects in a variety of agricultural crops (including, for example, melons, peaches, apples, grapes, sweet corn, lettuce, potatoes, carrots, cauliflower, cotton, beans, strawberries, tobacco, tomatoes), commercially-grown trees and shrubs, and commercially-grown greenhouse tomatoes. The EC formulation is proposed for use at an application rate ranging from (0.5 to 2.5 lbs a.i./acre), depending on the crop type and pest type. The 50WSB formulation, which is a wettable powder formulation packaged in water soluble bags, is proposed for use at label application rates ranging from 1 to 5 lbs formulation/acre (0.5 to 2.5 lbs a.i./acre). The Thiodan® 50WP product has use patterns that are very similar to those for Phaser® 50WSB. The major application methods are groundboom and aerial application to row crops and airblast application to tree crops; application via backpack sprayer is also addressed. The personal protective equipment specified by the labels are summarized in Table 6 below:

Table 6. Label-Specified Personal Protective Equipment (PPE) for Phaser® 3EC and Phaser® 50WSB As Applied to Mixing/Loading and Groundboom Application

Formulation	Label-Specified Personal Protective Equipment (PPE)						
	Coveralls	Short-Sleeve Shirt/Shorts	Long-Sleeve Shirt/Pants	Chemical-Resistant Gloves	Chemical-Resistant Footwear	Protective Eyewear/Headgear ^a	Organic Vapor Respirator ^b
Phaser 50WSB	✓	✓		✓	✓	✓	✓
Phaser 3EC	✓		✓	✓	✓	✓	✓
Thiodan 50WP	✓	✓		✓		✓	✓

^a Protective headgear is to be used when overhead applications are made.

^b Respirator with either an organic vapor-removing cartridge with a prefilter approved for pesticides or a canister approved for pesticides.

The labels also indicate that when handlers use closed systems such as closed cabs or aircraft in a manner consistent with the requirements of the Worker Protection Standards (WPS) for agricultural pesticides [40 CFR 170.40(d)(4-6)], the handler PPE requirements may be reduced or modified accordingly.

VI. OCCUPATIONAL HANDLER EXPOSURE/RISK ASSESSMENT

A. Handler Scenarios

The ETF agrees that there are potential exposures to mixers, loaders, applicators and other handlers (e.g., flaggers) during normal anticipated use of endosulfan. Based on anticipated and known use patterns, the following handler exposure scenarios were identified for endosulfan: (1a) mixing/loading of liquid formulations for aerial application; (1b) mixing/loading of liquid formulations for chemigation; (1c) mixing/loading of liquid formulations for groundboom application; (1d) mixing/loading of liquid formulations for airblast application; (1f) mixing and loading liquid formulations for plant and root dip; (2a) mixing/loading of wettable powder formulations for aerial application; (2b) mixing/loading of wettable powder formulations for groundboom application; (2c) mixing/loading of wettable powder formulations for airblast application; (2e) mixing/loading of wettable powder formulations for plant and root dip; (3) aerial application of liquid sprays; (4) groundboom application of liquid sprays; (5) airblast application of liquid sprays; (7) applying dip treatment to roots or whole plants; (11) mixing/loading/application of liquid formulations with a backpack sprayer; and (12) flagging of aerial spray applications. The following USEPA-identified handler exposure scenarios were not assessed because they are not uses that are supported by ETF labels for endosulfan: (1e) mixing/ loading of liquid formulations for rights-of-way application; (2d) mixing/loading of wettable powder formulations for rights-of-way applications; (6) rights-of-way applications; (8) mixing/loading and application of liquid formulations with a low-pressure hand wand; (9) mixing/loading and application of wettable powder formulations with a low-pressure hand wand; and (10) mixing/loading/application of liquid formulations with a high-pressure hand wand.

The current example labels for Phaser[®] 3EC, Phaser[®] 50WSB, and Thiodan[®] 50WP specify PPE during handling of the formulation. For application of Phaser[®] 3EC, the handler must wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves (such as barrier laminate or Viton[®] ≥ 14 mils), chemical-resistant footwear plus socks, protective eyewear, chemical-resistant headgear when overhead exposure is likely, and a respirator with either an organic vapor-removing cartridge with a prefilter approved for pesticides, or a NIOSH-approved respirator with an organic vapor removing cartridge or canister approved for pesticides. In addition, the handler must wear a chemical-resistant apron when mixing/loading or cleaning equipment. For application of Phaser[®] 50WSB, the handler must wear coveralls over short-sleeved shirt and short pants, waterproof gloves, chemical-resistant footwear plus socks, protective eyewear, chemical-resistant headgear when overhead exposure is likely, and a respirator with either an organic vapor-removing cartridge with a prefilter approved for pesticides, or a canister approved for pesticides. In addition, the handler must wear a chemical-resistant apron when mixing/loading or cleaning equipment. The PPE specified by the Thiodan[®] 50WP label is the same as for Phaser[®] 50WSB, except that the use of chemical-resistant footwear is not specifically required.

B. Surrogate Worker Exposure Data

The Pesticide Handlers Exposure Database (PHED), Version 1.1, was used as the source of surrogate worker exposure data for estimation of mixer/loader, applicator, and flagger exposures. This database, which contains exposure monitoring data and other ancillary data for over 1,700 worker replicates, was used to develop exposure estimates (normalized by lb a.i. handled) for the inhalation route, hand, and “other” dermal areas. PHED was developed as a joint effort of the USEPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association. The appropriate data subsetting criteria to use are described in the PHED guidance documents (USEPA 1995a, 1995b). Part of the subsetting criteria include the quality of the data based on the available quality control data (e.g., percent recovery, variability in the recovery data) associated with the data, which forms the basis for the grading system for data quality. Because each worker replicate is graded separately, it is recommended that separate data sets be developed to address inhalation, hand, and “other” dermal exposures. PHED also specifies a “best fit” total dermal exposure based on a composite of the appropriate central tendency values for each body part. For this composite, the PHED guidance documents (USEPA 1995a, 1995b) state that the central tendency is the arithmetic mean for a body part for which the exposure data are normally distributed, the geometric mean for a body part for which the exposure data are lognormally distributed, and the median (i.e., 50th percentile) for a body part for which the exposure data are distributed other than normally or lognormally. HED has developed a series of default tables of normalized exposure values for many handler scenarios (USEPA 1998a), the specific data sets were investigated to quantitatively examine the impact of clothing and other personal protective equipment (PPE) on body part-specific and composite exposures. The individual data sets from PHED, Version 1.1, as represented in the surrogate PHED exposure guide (USEPA 1998a) are described below.

(1) Normalized exposure data for open mixing/loading of liquid formulations.

The Mixer/Loader files of PHED, Version 1.1, contain data for inhalation exposures, hand exposures, and “other” dermal exposures associated with mixing and loading of liquid formulations outdoors. For the surrogate exposure guide for this worker scenario (USEPA 1998a), worker replicates were subset to represent open mixing/loading of all liquid formulation types. When the data were subset to capture data of PHED grade quality A and B, 85 replicates of inhalation data, 59 replicates of hand data (with protective gloves), and 72 to 122 worker replicates of “other” dermal data (depending on the body part) were obtained. “Other” dermal data are for the PPE scenarios long-sleeve shirt and long pants. The central tendency values for normalized exposures associated with open mixing/loading of liquid formulations are provided in Table 7.

Table 7. Normalized Mixer/Loader Exposure Data From PHED

Handler Scenario	Exposure Route	Distribution Type	Normalized Exposure ($\mu\text{g/lb a.i.}$) ^a	Comments
Open Mixing/Loading of Liquids	Inhalation	Other	1.2 [M]	N = 85; Grade A & B data
	Hands	Lognormal	6.71 [GM]	N = 59; Gloves; Grades A, B
	Other Dermal ^b	----	16.27 [BF] LPLS ^c	N = 72 to 122; Grades A & B data
Open Mixing/Loading of Wettable Powder Formulation ^d	Inhalation	Lognormal	43.42 [GM]	N = 44; Grades ABC
	Hands	Lognormal	13.8 [GM]	N = 24; Gloves; Grades ABC
	Other Dermal	----	153.6 [BF] LPLS ^c	N = 22 to 45; Grades ABC

Endnotes:

^a Abbreviations: M = median (i.e. 50th percentile), GM = geometric mean; AM = arithmetic mean; BF = best fit.

^b Other dermal exposure defined as “best fit” total dermal exposure minus central tendency hand exposure; includes exposures to the head, neck, upper arms, lower arms, chest, back, thigh, and lower leg.

^c LPLS = long pants and long-sleeve shirt.

^d Excluding water soluble packets.

(2) *Normalized exposure data for open mixing/loading of wettable powder formulations.* Normalized exposures associated with open mixing/loading of wettable powder formulations in the PHED surrogate exposure guide (USEPA 1998a) were obtained from the Mixer/Loader file of PHED, Version 1.1. Subsetting conditions included mixing procedure = open, solid formulations = wettable powder, excluding water soluble packets. Because of the number of data replicates did not equal or exceed the Subdivision U-required minimum of 15 replicates (USEPA 1984) for inhalation, hands, or “other” dermal exposures when subsets were restricted to A and B grades only, the data sets were expanded by specifying grades A, B or C. When the data were subset separately to capture data of PHED grade quality A, B and C, 44 replicates of inhalation data, 24 replicates of hand data (with protective gloves), and 22 to 45 worker replicates of “other” dermal data (depending on the body part) were obtained. The central tendency values for normalized exposures associated with open mixing/loading of wettable powder formulations are provided in Table 7.

(3) *Normalized exposure data for aerial application.* Normalized exposures associated with aerial fixed-wing application in the PHED surrogate exposure guide (USEPA 1998a) were obtained from the Applicator file of PHED, Version 1.1. Because very few replicates were found for open cab settings¹, the data were subset for all liquid formulation types and closed cab².

¹Open cab is defined as open cab or closed cab with window open

²Closed cab is defined as closed cab with window closed, or closed cab with filtered air.

In order to obtain an adequate number of replicates for inhalation exposures, the grade subsetting was expanded to include A, B, and C quality assurance grades (23 replicates). The Subdivision U (USEPA 1984) minimum of 15 worker replicates was not met for hand data with protective gloves, even when A, B and C grades were included. Without protective gloves, 34 replicates were obtained when the data were restricted to A and B grade data. Normalized dermal data involving 24 to 48 worker replicates (depending on the body part) were obtained for the long-sleeve shirt/long pants clothing scenario for A, B and C quality assurance grades. The central tendency values for normalized exposures associated with closed cab aerial application of liquid sprays are provided in Table 8.

(4) Normalized exposure data for groundboom application. Normalized exposures in the PHED surrogate exposure guide (USEPA 1998a) associated with open-cab groundboom application of sprays were obtained from the Applicator file of PHED, Version 1.1. When PHED data quality grades were restricted to A and B, 22 worker replicates were obtained for inhalation exposures, and 23 to 42 replicates were obtained for dermal exposure, depending on the body part. If the PHED grades were restricted to A and B only, an inadequate number of replicates (i.e., less than 15) were obtained for hands with protective gloves; however, an adequate number of replicates was obtained for hands without protective gloves, yielding 29 replicates of high confidence A and B data. The central tendency values for normalized exposures for open cab groundboom application of liquid sprays are provided in Table 8.

(5) Normalized exposure data for airblast application. Normalized exposure data associated with open-cab airblast application for the PHED surrogate exposure guide (USEPA 1998a) were obtained from the Applicator file of PHED, Version 1.1. Data were restricted to replicates for trees and grapes (data from Study 0510 on turf was eliminated from the data set), and open cab settings for all formulation types for which airblast application is relevant. When PHED data quality grades were restricted to A and B, a total of 47 replicates were obtained for inhalation exposures and 18 replicates were obtained for hand exposures (with protective gloves). Subsetting of dermal exposure data based on A and B data quality grades yielded 31 to 48 high-confidence replicates. Dermal exposure data were obtained for the clothing scenarios long-sleeve shirt and long pants. The central tendency values for normalized exposures associated with open cab airblast application of liquid sprays are provided in Table 8.

(6) Normalized exposure data for backpack application. Normalized exposure data in the PHED surrogate exposure guide (USEPA 1998a) for application of sprays using backpack equipment were obtained from the Mixer/Loader/Applicator file of PHED, Version 1.1. Only limited data of low confidence are available. When all quality assurance grades were permitted, only 11 replicates of inhalation data, 2 replicates of hand data, and 9 to 11 replicates of dermal exposures data were available. The central tendency values for normalized exposures associated with backpack application of liquid sprays are provided in Table 8.

Table 8. Normalized Applicator and Flagger Exposure Data From PHED

Handler Scenario	Exposure Route	Distribution Type	Normalized Exposure ($\mu\text{g/lb a.i.}$) ^a	Comments
Closed Cab Aerial Application of Liquids (fixed-wing aircraft)	Inhalation	Lognormal	0.068 [GM]	N = 23; Grades A, B & C
	Hands	Lognormal	3.11 [GM]	N = 34; No Gloves; A B data
	Other Dermal ^b	----	1.90 [BF] LPLS ^c	N = 24 to 48; A, B, & C grade data
Open Cab Groundboom Application	Inhalation	Lognormal	0.74 [GM]	N = 22; Grades A & B
	Hands	Lognormal	6.50 [GM]	N = 29; No Gloves; AB Data
	Other Dermal	----	7.73 [BF] LPLS ^c	N = 23 to 42; Grades A & B
Open Cab Airblast Application	Inhalation	Other	4.5 [M]	N = 47; Grades A & B
	Hands	Lognormal	2.43 [GM]	N = 18; Gloves; Grades A,B
	Other Dermal	----	239 [BF] LPLS ^c	N = 31 to 48; Grades A & B; head + neck = 197 $\mu\text{g/lb a.i.}$
Backpack Application	Inhalation	Other	30 [M]	N = 11; Grades A & B
	Hands	Lognormal	4.62 [GM]	N = 11; Gloves; Grades A , B, & C
	Other Dermal	----	2,462 [BF] LPLS ^c	N = 9 to 11; Grades A & B
Flagging Aerial Spray Operations	Inhalation	Normal	0.35 [AM]	N = 28; Grades A & B
	Hands	Lognormal	2.72 [GM]	N = 30; No Gloves; AB Data
	Other Dermal	----	8.37 [BF] LPLS ^c	N = 18 to 28; Grades A & B; head + neck = 6.63 $\mu\text{g/lb a.i.}$

Endnotes:

^a Abbreviations: M = median (i.e. 50th percentile), GM = geometric mean; AM = arithmetic mean; BF = best fit.

^b "Other" dermal exposure defined as "best fit" total dermal exposure minus central tendency hand exposure.

^c LPLS = long pants and long-sleeve shirt.

(7) Normalized exposure data for flagging aerial spray operations. Normalized exposure data for flagging aerial spray operations in the surrogate exposure guide (USEPA 1998a) were obtained from the Flagger file of PHED, Version 1.1. Data for flagging aerial application of granular formulations (PHED study codes 0448 and 1003 on rice) were not included in the data subset. When PHED data quality grades were restricted to A and B, a total of 28 replicates were obtained for inhalation exposures and 30 replicates were obtained for hand exposures without protective gloves. An inadequate number (6) of grade A and B quality hand exposure data were obtained for the use of protective gloves. Subsetting of dermal exposure data based on A and B data quality grades yielded a total of 18 to 28 replicates. Dermal exposure data were obtained for the clothing scenario long pants and long-sleeve shirt. The central tendency values for normalized exposures associated with the flagging of aerial spray application of liquid sprays are provided in Table 8.

(8) Normalized exposure data for mixing/loading of wettable powder formulations in water soluble bags. Normalized exposure data in the PHED surrogate exposure guide (USEPA 1998a) for mixing/loading operations involving wettable powder formulations packaged in water soluble bags were obtained from the Mixer/Loader file of PHED, Version 1.1. When the data were subset based on A and B quality assurance grades, only 5 replicates were obtained for hand exposure data (without gloves) and from 6 to 15 replicates per body part were obtained for dermal exposure. Dermal exposure data were obtained for the clothing scenario long pants and long-sleeve shirt. In order to obtain an adequate number of inhalation exposure replicates, the data were subset for all airborne grades, in which case 15 replicates were obtained. The central tendency values for normalized exposures associated with the flagging of aerial spray application of liquid sprays are provided in Table 9.

(9) Normalized exposure data for closed-cab airblast application. Normalized exposure data in the PHED exposure surrogate guide (USEPA 1998a) for airblast application of sprays using enclosed cabs were obtained from the Applicator file of PHED, Version 1.1. When the data were subset based on A and B quality data, 20 replicates were obtained for hand exposure data (with protective gloves), and from 20 to 30 replicates per body part were obtained for dermal exposures. When A, B and C grade airborne data were specified, only 9 replicates of inhalation exposure data were obtained. The central tendency values for normalized exposures associated with closed cab airblast application of liquid sprays are provided in Table 9.

Table 9. Normalized PHED Exposure Data for Engineering Control Scenarios

Handler Scenario (Engineering Controls)	Exposure Route	Distribution Type	Normalized Exposure ($\mu\text{g/lb a.i.}$) ^a	Comments
Open Mixing/Loading of Wettable Powder Formulations (Water Soluble Packets)	Inhalation	Lognormal	0.24 [GM]	N = 15; Grade ABCDE data
	Hands	Lognormal	11.2 [GM]	N = 5; No Gloves, Grades A, B
	Other Dermal ^b	----	9.74 [BF] LPLS ^c	N = 6 to 15; Grades A & B data
Airblast Application (Closed Cab)	Inhalation	Lognormal	0.45 [GM]	N = 9; Grades A, B, C
	Hands	Lognormal	12.9 [GM]	N = 20; Gloves; Grades A, B
	Other Dermal	----	6.04 [BF] LPLS ^c	N = 20 to 30; Grades A, B

Endnotes:

^a Abbreviations: M = median (i.e. 50th percentile), GM = geometric mean; AM = arithmetic mean; BF = best fit.

^b "Other" dermal exposure defined as "best fit" total dermal exposure minus central tendency hand exposure.

^c LPLS = long pants and long-sleeve shirt.

C. Adjustment of Normalized PHED Data for Clothing and PPE Scenarios

The normalized mixer/loader, applicator, and flagger exposure data from Tables 7, 8 and 9, respectively, were adjusted to reflect the Personal Protective Equipment (PPE) specified on the product labels. Similarly, the normalized exposure data for the addition of engineering controls (Table 9) were adjusted as appropriate to represent the anticipated PPE scenarios. Starting data sets for "other dermal" exposure (i.e., total dermal exposure minus hand exposure) were obtained for the PPE scenario "long pants, long-sleeve shirt". Thus, where the label specifies the use of coveralls, the normalized body part-specific exposure data for "other dermal" for the long pants/long-sleeve shirt scenario were typically adjusted by dividing the exposures for those body parts typically covered by coveralls (i.e., upper arms, chest, back, forearms, thighs, and lower legs) by a factor of 2 (i.e., 50 percent reduction in exposures for protective clothing). Where an organic vapor-removing cartridge or canister-type respirator is used with an appropriate pre-filter, a 10-fold protection factor is used to reduce the inhalation exposure estimates. If the label specified the use of gloves, but sufficient exposure data for the PPE scenario "gloves" were not available, the hand exposure data for the PPE scenario "no gloves" were divided by a factor of 10 to represent the 90 percent reduction in exposures anticipated with the use of chemical-resistant gloves. The converse (i.e., increasing gloved hand exposures by 10 to account for "ungloved" hands) was not done for closed cab exposure scenarios. The ETF had previously pointed out to the Agency the error of back-calculating bare-hand exposures from gloved-hand exposure data for closed cab scenarios, where a high-level of protection from dermal exposure is already provided by the engineering controls.

In situations where protective headgear is worn (such as in the case of open cab airblast

application, where overhead exposures are anticipated), a 50 percent protection factor was applied. In its response to Registrant comments on the occupational exposure/risk assessment (USEPA 2001b), the Agency has indicated its reluctance to accept the 50 percent exposure reduction factor for protective headgear. The registrant acknowledges that protective headgear are available in a variety of styles and designs; the Agency acknowledges that protective headgear would be anticipated to reduce head and neck exposures, where the potential for overhead exposures is present (e.g., for airblast application and flagging operations). However, until quantitative data are available, it is recommended that a 50 percent protection factor be used as a conservative professional judgement until the Agency is able to specify an alternative value. Therefore, this adjustment has been retained in the assessment provided here.

An example of adjustment of PHED data is shown in Table 10 for the case of open-cab airblast application. The subset is for open-cab airblast application of sprays to trees and grapes; this is the subset selected by the USEPA in the PHED surrogate exposure guide (USEPA 1998a). These data are matched with the PPE requirements of the example labels by adjusting the central-tendency body part-specific exposures as follows:

- Exposure values for body parts covered by coveralls are reduced by a factor of 2 to represent a 50 percent protection factor (Table 10, value B3);
- Exposure values for the head, neck front, and neck back are reduced by 50 percent to represent the use of protective headgear (Table 10, value C1);
- Hand exposure data are not adjusted because it already represents exposures with protective gloves, as required by the label for all handlers (Table 10, value A2); and
- The fully adjusted central tendency body-part specific exposures are then summed (Table 10, values D1 + D2 + D3).

Table 10. Adjustment of Normalized PHED Exposure Data Open Cab Airblast Application (Long Pants, Long Sleeves) to Represent Label Requirements of Coveralls Over Long Pants Long Sleeves, and Protective Headgear

Body Part	Distribution Type	Central-Tendency Body Part-Specific Exposures (µg/lb a.i.) ^a (A)	Adjusted Exposure for Coveralls ^b (B)	Adjusted Exposure for Protective Headgear ^c (C)	Adjusted Central Tendency Values for Summation (µg/lb a.i.) (D)
(1) Head and Neck	Lognormal	197	----	98.5	98.5
(2) Hands	Lognormal	2.43	----	----	2.43 ^e
(3) Chest, Back, Arms, and Legs	Lognormal	42.1	21.05	----	21.05
(4) Feet	----	ND ^d	----	----	----
Sum of Adjusted Central Tendency Body Part Total Dermal Exposures =					122

^a Central-tendency exposures are defined in PHED as the geometric mean if the body part exposure data are lognormally distributed, the arithmetic mean if the body part exposure data are normally distributed, and the median if the body part exposure data are distributed in some other fashion.

^b Exposure values for areas covered by coveralls are reduced by a factor of 2 (i.e., 50 percent protection factor); these areas include the upper arms, chest, back, forearms, thighs, and lower legs.

^c Head, neck front, and neck back exposures are conservatively reduced by a factor of 2 to represent the use of protective headgear.

^d ND = No data available in the data subset for this body part.

^e No adjustment of the hand data are necessary as the starting data are for hands with protective gloves.

D. Estimation of Short-Term Handler Exposures to Endosulfan

(1) Assumptions. Short-term handler exposures are defined as consisting of 1 to 30 days in duration. Some of the assumptions used by the Endosulfan Task Force (ETF) in this assessment of handler exposures are similar to those used in the Agency's revised assessment (USEPA 2001a), although there are some notable differences (e.g., with regard to assigned protection factors). The following assumptions and parameter values were used:

- Daily duration of exposure = 8 hours
- Average body weight of adult handler = 70 kg³
- Acres treated per day:
 - 350 acres/day for aerial treatment of crops other than small grains (wheat, barley, oats, rye), cotton, corn, and clover;
 - 600 acres/day: aerial treatment: small grains, cotton, corn, clover;⁴
 - 350 acres/day for flaggers supporting aerial application;
 - 200 acres/day for groundboom treatment of small, grains, cotton, clover, and corn;
 - 80 acres/day for groundboom treatment of other crops;
 - 40 acres for airblast applications on agricultural crops;
 - 10 acres per day for airblast application to ornamentals⁵
- Protection factors:
 - Chemical-resistant gloves: 10-fold protection for hand exposures;⁶
 - Protective clothing: 50-percent protection factor for dermal exposure for body parts covered by coveralls;
 - Respirator: 10-fold protection factor for organic vapor-cartridge or -canister respirator with an approved pre-filter;
 - Protective headgear: 50 percent protection factor applied.
- Respiratory absorption: 100 percent

³If developmental or female reproductive effects had been a toxicity endpoint of concern for endosulfan, a body weight of 60 kg would have been used in the assessment.

⁴California default values for number of acres treated per day by one aerial applicator, based on Nov. 10, 1999 and Nov. 19, 1999 personal communications with Michael Dong and David Haskell, respectively, of the California Department of Pesticide Regulation, Worker Health and Safety Branch. Aerial application of 600 acres/day is felt to be a much more reasonable high-end default than the 1,200 acres per day used by the Agency.

⁵Because most ornamental growing operations are limited in size, the Endosulfan Task Force believes that 10 acres/day is a much more reasonable default value than assuming 40 acres treated per day for ornamentals.

⁶Waterproof gloves are considered chemically-resistant for WP formulations due to the lack of solvent; in the case of EC formulations, barrier laminate or Viton gloves are to be used.

- Worker inhalation rate: 1.74 m³/hr (29 liters/min)

(2) Calculation of short-term handler exposures to endosulfan. Handler exposure calculations were made using the actual label-recommended personal protective equipment and clothing (PPE) and using additional engineering controls as separate scenarios. Exposure calculations for the baseline clothing scenario are not developed here, because they violate basic label conditions and the Worker Protection Standards, and are viewed by the Endosulfan Task Force as being potentially misleading. The exposure scenarios and supporting PHED data are summarized in Table 11. Short-term exposures for handlers for the label-specified PPE are provided in Table 12. Table 13 provides the estimated short-term exposures for handlers where additional PPE and engineering controls are employed.

Daily dermal doses (E_d) to handlers were estimated using the following equation.

$$E_d \text{ (mg/kg/day)} = \text{Normalized Unit Exposure (mg a.i./lb a.i.)} \times \text{Use Rate (lb a.i./acre)} \\ \times \text{Area Treated (acres/day)} \times [1/\text{body weight (kg)}]$$

In the case of mixing/loading formulations for plants and root dip, and mixing/loading/applying sprays with backpack equipment, the dermal exposure is estimated as follows:

$$E_d \text{ (mg/kg/day)} = \text{Normalized Unit Exposure (mg a.i./lb a.i.)} \times \text{Concentration (lb a.i./gallon)} \\ \times \text{Volume Applied (gallons/day)} \times [1/\text{body weight (kg)}]$$

Because the dermal toxicity endpoint was based on a dermal study, a dermal absorption factor is not applied.

The short-term inhalation doses (E_{inh}) to handlers were estimated using the following equation:

$$E_{inh} \text{ (mg/kg/day)} = \text{Normalized Unit Exposure (}\mu\text{g a.i./lb a.i.)} \times \text{Conversion Factor (mg/1,000 }\mu\text{g)} \\ \times \text{Use Rate (lb a.i./acre)} \times \text{Area Treated (acres/day)} \times [1/\text{body weight (kg)}]$$

In the case of mixing/loading formulations for plants and root dip, and mixing/loading/applying sprays with backpack equipment, the inhalation exposure is estimated as follows:

$$E_{inh} \text{ (mg/kg/day)} = \text{Normalized Unit Exposure (}\mu\text{g a.i./lb a.i.)} \times \text{Conversion Factor (mg/1,000 }\mu\text{g)} \times \\ \text{Concentration (lb a.i./gallon)} \times \text{Volume Applied (gallons/day)} \times [1/\text{body weight (kg)}]$$

Due to the largely nonrespirable nature of applied aerosols, it is assumed that the aerosols are cleared from the upper respiratory tract and swallowed, being completely converted to an oral dose, conservatively assuming 100 percent absorption in the gut.

E. Estimation of Margins-of-Exposure

The Margins-of-Exposure (MOEs) were calculated by dividing the dermal or inhalation NOAEL by the short-term dermal or inhalation dose, respectively. A short-term NOAEL of 12 mg/kg/day based on the 21-day dermal study in rats was used to calculate the MOEs associated with dermal exposures. A short-term *oral* NOAEL of 1.5 mg/kg/day (based on the acute oral neurotoxicity study in rats) was used to estimate the MOEs associated with worker inhalation exposures that are cleared to the gut. For reasons previously noted (see Section III), the short-term NOAEL from the rat inhalation study was not used due to extreme differences between the mean diameter of the particle sizes administered in the study and the substantially larger mean diameters of aerosols produced by agricultural application equipment. Dermal and inhalation exposures and MOEs were not aggregated due to the potential route-specific differences in toxicology and the different route-specific NOAELs.

Table 11. Occupational Exposure Scenario Descriptions for the Use of Endosulfan

Exposure Scenario (Scenario No.)	Data Source	Standards Assumptions (8-hr work day) ^a	Comments ^b
Mixer/Loader Descriptors			
Mixing/Loading of Liquid Formulations (1a/1b/1c/1d/1f)	PHED V 1.1	600 acres for aerial application on small grains, cotton, corn, and alfalfa; 350 acres for aerial application on all other crops and for chemigation; 200 acres for groundboom application to cotton, wheat, alfalfa, and corn; 80 acres for groundboom application to all other agricultural crops; 10 acres for application to ornamentals; 40 acres for airblast application to fruit and nut trees; 100 gallons for plant/root dip.	<p>Label PPE: Hands, dermal and inhalation = AB grades. Hands = 59 replicates; dermal = 72 to 122 replicates; and inhalation = 85 replicates. High confidence in hands, dermal, and inhalation data. A 50 percent protection factor for dermal areas covered by protective clothing; a 90 percent protection factor for inhalation exposures for use of organic vapor-removing respirator. Hand data are for gloved hands, so no additional protection factor is applied for gloves.</p> <p>Engineering Controls: None Applied</p>
Mixing/Loading of Wettable Powder Formulations (2a/2b/2c/2e)	PHED V 1.1	600 acres for aerial application on small grains, cotton, corn, and alfalfa; 350 acres for aerial application on all other crops and for chemigation; 200 acres for groundboom application to cotton, wheat, alfalfa, and corn; 80 acres for groundboom application to all other agricultural crops; 10 acres for application to ornamentals; 40 acres for airblast application to fruit and nut trees; 100 gallons for plant/root dip.	<p>Label PPE: Hands, dermal, and inhalation = ABC grades. Hands = 24 replicates; dermal = 22 to 45 replicates, and inhalation = 44 replicates. Medium confidence in dermal, hand, and inhalation data. A 50 percent protection factor for dermal areas covered by protective clothing; 90 percent protection factor for inhalation exposures for organic vapor-removing respirator with appropriate pre-filter. Hand data are for gloved hands, so no additional protection factor is applied for hands.</p> <p>Engineering Controls: Hands and dermal = AB grades; inhalation = all grades. Hands = 5 replicates; dermal = 6 to 15 replicates; and inhalation = 15 replicates. Low confidence in hand, dermal, and inhalation data, based on low number of replicates or poor grades (inhalation). 90 percent protection factor applied to hand data (without gloves) to represent protective gloves. Engineering controls based on water soluble packets.</p>
Applicator Descriptors			
Applying Sprays with Aerial Equipment (3)	PHED V 1.1	600 acres for aerial application on small grains, cotton, corn, and alfalfa; 350 acres for aerial application on all other crops	<p>Label PPE: Hand data = AB grades; inhalation and dermal data = ABC grades. Hands = 34 replicates; dermal = 24 to 48 replicates; and inhalation = 23 replicates. Medium confidence in dermal and inhalation data; high confidence in hand data. Hand data are for without protective gloves, and are not adjusted to reflect use of reduced PPE in closed cockpit.</p> <p>Engineering Controls: None applied.</p>
Applying Sprays with Groundboom Equipment (4)	PHED V 1.1	200 acres for groundboom application to cotton, wheat, alfalfa, and corn; 80 acres for groundboom application to all other agricultural crops; 10 acres for ornamentals	<p>Label PPE: Dermal, hand, and inhalation data = AB grades. Hands = 29 replicates; dermal = 23 to 42 replicates, and inhalation = 22 replicates. High confidence in hands, dermal, and inhalation data. A 50 percent protection factor for dermal areas covered by protective clothing; 90 percent protection factor for inhalation exposures for use of organic vapor-removing respirator with appropriate pre-filter. Hand data are without gloves, so 90 percent protection factor applied for protective gloves.</p> <p>Engineering Controls: None applied.</p>

Table 11. Occupational Exposure Scenario Descriptions for the Use of Endosulfan (continued)

Exposure Scenario (Scenario No.)	Data Source	Standard Assumptions (8-hr work day) ^a	Comments ^b
Applicator Descriptors (continued)			
Applying Sprays with an Airblast Sprayer (5)	PHED V 1.1	40 acres for application to fruit/nut; 10 acres for ornamental trees	<p>Label PPE: Hands, dermal, and inhalation data = AB grades. Hands = 18 replicates; dermal = 31 to 48 replicates; inhalation = 47 replicates. High confidence in hands, dermal, and inhalation data. A 50 percent protection factor for dermal areas covered by protective clothing, including coveralls and protective headgear; 90 percent protection factor for inhalation exposures to account for use of organic vapor-removing respirator with appropriate pre-filter. No protection factor needed to define hand exposures because data are for gloved hands.</p> <p>Engineering Controls: Hands and dermal data = AB grades; inhalation data = ABC grades. Dermal = 20 to 30 replicates; hand = 20 replicates; inhalation = 9 replicates. High confidence in hand and dermal data; low confidence in inhalation data (based on low number of replicates). Gloved hand data not increased by 10 to reflect reduced PPE in closed cab, because enclosed cab already provides a high level of protection from dermal exposure.</p>
Application of Sprays to Rights-of-Way (6)	-----	-----	Not relevant to label uses; therefore, not assessed.
Application of Dip Treatment to Roots or Whole Plants (7)	No Data	100 gallons/day for root, dip, and whole strawberry plant treatment	No Data
Mixer/Loader/Applicator Descriptors			
Mixing/Loading/Applying Liquids With a Low- Pressure Hand Wand (8)	-----	-----	Not relevant to label uses; therefore, not assessed
Mixing/Loading/Applying Wettable Powders With a Low-Pressure Hand Wand (9)	-----	-----	Not relevant to label uses; therefore, not assessed
Mixing/Loading/Applying Liquids Using a High- Pressure Sprayer (10)	-----	-----	Not relevant to label uses; therefore, not assessed
Mixing/Loading/Applying Liquids With a Backpack Sprayer (11)	PHED V 1.1	40 gallons/day for ornamental trees and shrubs, greenhouse tomatoes and related applications.	Label PPE: Dermal and inhalation data = AB grades; hand data = ABC grades. Hands = 11 replicates; dermal = 9 to 11 replicates, and inhalation = 11 replicates. Low confidence in dermal, hand, and inhalation data. A 50 percent protection factor for dermal areas covered by protective clothing; 90 percent protection factor for inhalation exposures for organic vapor-removing respirator with appropriate pre-filter. Hand data are for gloved hands, so no adjustment needed.

Table 11. Occupational Exposure Scenario Descriptions for the Use of Endosulfan (continued)

Exposure Scenario (Scenario No.)	Data Source	Standard Assumptions (8-hr work day) ^a	Comments ^b
Flagger Descriptors			
Flagging Aerial Spray Applications (12)	PHED V 1.1	350 acres treated per day	<p>Label PPE: Hands, dermal, and inhalation data = AB grades. Hand = 30 replicates; dermal = 18 to 28 replicates; inhalation = 28 replicates. High confidence in hand, dermal, and inhalation data. A 50 percent protection factor for dermal areas covered by protective clothing (including coveralls and protective headgear); 90 percent protection factor for inhalation exposures to account for use of organic vapor-removing respirator with appropriate pre-filter. Hand data are without gloves, so 90 percent protection factor applied to represent covered hands.</p> <p>Engineering Controls: None applied.</p>

Footnotes:

^a Standard assumptions based on an 8-hour work day.

^b “Best available” grades are defined by OREB SOP for meeting Subdivision U Guidelines, assigned as follows: matrices with grades A and B *and* a minimum of 15 replicates; if not available, then grades A, B, and C data and a minimum of 15 replicates, if available; then all data regardless of quality and number of replicates. Data confidence assigned as follows:

High = grades A and B; 15 or more replicates per body part

Medium = grades A, B, and C; 15 or more replicates per body part

Low = grades A, B, C, D, and E, *or* any combination of grades with less than 15 replicates.

Table 12. Short-Term Occupational Handler Exposures and Risks From Endosulfan Under Label PPE Assumptions^a

Exposure Scenario (Scenario No.)	Crop Type/Use	Dermal Unit Exposure (mg/ lb a.i.)	Inhalation Unit Exposure (µg/lb a.i.)	Application Rate (lb a.i./acre)	Area Treated per Day (acres/day)	Daily Dermal Dose ^b (mg/kg/d)	Daily Inhalation Dose ^c (mg/kg/d)	Dermal MOE ^d	Inhalation MOE ^e
Mixer/Loader Exposures									
Open Mixing/Loading of Liquid Formulations for Aerial Application (1a)	clover	0.017	0.12	0.5	350	0.043	0.00030	280	5,000
	tobacco			1.0	350	0.085	0.00060	140	2,500
	pecans			3.0	350	0.26	0.0018	47	830
	small grains			0.75	600	0.11	0.00077	110	1,900
	cotton			1.5	600	0.22	0.0015	55	1,000
Open Mixing/Loading of Liquid Formulation for Chemigation (1b)	potatoes (Idaho)	0.017	0.12	1.0	350	0.085	0.00060	140	2,500
Open Mixing/Loading of Liquid Formulation for Groundboom Application (1c)	clover	0.017	0.12	0.5	80	0.0097	0.000069	1,200	22,000
	tobacco			1.0	80	0.019	0.00014	620	11,000
	small grains			0.75	200	0.036	0.00026	330	5,800
	cotton			1.5	200	0.073	0.00051	160	2,900
Open Mixing/Loading of Liquid Formulation for Airblast Application (1d)	ornamental trees/shrubs	0.017	0.12	3.0	10	0.0073	0.000051	1,600	29,000
	hazelnuts			2.0	40	0.019	0.00014	620	11,000
	pecans			3.0	40	0.029	0.00021	410	7,300
Open Mixing/Loading of Liquids for Rights-of-Way Application (1e)	Not relevant to label uses; therefore, not assessed								
Open Mixing/Loading of Liquids for Plant and Root Dip (1f)	cherry, peach, plums	0.017	0.12	0.05 lbs a.i./gal	100 gal/day	0.0012	0.0000086	9,900	180,000

Table 12. Short-Term Occupational Handler Exposures and Risks From Endosulfan Under Label PPE Assumptions (Continued)

Exposure Scenario (Scenario No.)	Crop Type/Use	Dermal Unit Exposure (mg/ lb a.i.) ^a	Inhalation Unit Exposure (µg/lb a.i.)	Application Rate (lb a.i./acre)	Area Treated per Day (acres/day)	Daily Dermal Dose ^b (mg/kg/d)	Daily Inhalation Dose ^c (mg/kg/d)	Dermal MOE ^d	Inhalation MOE ^e
Mixer/Loader Exposures (Continued)									
Open Mixing/Loading of Wettable Powders for Aerial Application (2a)	beans	0.13	4.3	1.0	350	0.65	0.022	18	70
	sweet potatoes			2.0	350	1.3	0.043	9	35
	peaches			2.5	350	1.6	0.054	7	28
	small grains			0.75	600	0.84	0.028	14	54
	cotton			1.5	600	1.7	0.055	7	27
Open Mixing/Loading Wettable Powders for Groundboom Application (2b)	beans	0.13	4.3	1.0	80	0.15	0.0049	81	310
	sweet potatoes			2.0	80	0.30	0.0098	40	150
	small grains			0.75	200	0.28	0.0092	43	160
	cotton/tobacco			1.5	200	0.56	0.018	22	81
Open Mixing/Loading Wettable Powders for Airblast Application (2c)	ornamental trees/shrubs	0.13	4.3	3.0	10	0.056	0.0018	220	810
	hazelnuts			2.0	40	0.15	0.0049	81	310
	peaches			2.5	40	0.19	0.0061	65	240
Open Mixing/Loading Wettable Powders for Rights- of-Way Spray Treatment (2d)	Not relevant to label uses; therefore, not assessed								
Open Mixing/Loading Wettable Powders for Plants and Root Dip (2e)	cherry, peach, plums	0.13	4.3	0.05 lb a.i./gal	100 gal/day	0.0093	0.00031	1,300	4,900

Table 12. Short-Term Occupational Handler Exposures and Risks From Endosulfan Under Label PPE Assumptions (Continued)

Exposure Scenario (Scenario No.)	Crop Type/Use	Dermal Unit Exposure (mg/ lb a.i.) ^a	Inhalation Unit Exposure (µg/lb a.i.)	Application Rate (lb a.i./acre)	Area Treated per Day (acres/day)	Daily Dermal Dose ^b (mg/kg/d)	Daily Inhalation Dose ^c (mg/kg/d)	Dermal MOE ^d	Inhalation MOE ^e
Applicator Exposures									
Applying Spray With Aerial Equipment (3)	clover	0.0050	0.068	0.5	350	0.013	0.00017	960	8,800
	tobacco			1.5	350	0.038	0.00051	320	2,900
	pecans			3.0	350	0.075	0.0010	160	1,500
	small grains			0.75	600	0.032	0.00044	370	3,400
	cotton			1.5	600	0.064	0.00087	190	1,700
Applying Sprays With a Groundboom Sprayer (4)	clover	0.0053	0.074	0.5	80	0.0030	0.000042	4,000	35,000
	tobacco			1.5	80	0.0091	0.00013	1,300	12,000
	small grains			0.75	200	0.011	0.00016	1,100	9,500
	cotton			1.5	200	0.023	0.00032	530	4,700
Applying Sprays With an Airblast Sprayer ^f (5)	ornamental trees	0.12	0.45	3.0	10	0.051	0.00019	230	7,800
	hazelnuts			2.0	40	0.14	0.00051	88	2,900
	pecans			3.0	40	0.21	0.00077	58	1,900
Applying Sprays With a Rights-of-Way Sprayer (6)	Not relevant to label uses; therefore, not assessed								
Applying Dip Treatment to Roots or Whole Plants (7)	cherry, peach, plum	No Data	No Data	0.05 lbs a.i./gal	100 gal/day	No Data	No Data	No Data	No Data

Table 12. Short-Term Occupational Handler Exposures and Risks From Endosulfan Under Label PPE Assumptions (Continued)

Exposure Scenario (Scenario No.)	Crop Type/Use	Dermal Unit Exposure (mg/ lb a.i.) ^a	Inhalation Unit Exposure (µg/lb a.i.)	Application Rate (lb a.i./acre)	Area Treated per Day (acres/day)	Daily Dermal Dose ^b (mg/kg/d)	Daily Inhalation Dose ^c (mg/kg/d)	Dermal MOE ^d	Inhalation MOE ^e
Mixer/Loader/Applicator Exposures									
Mixing/Loading/Applying Liquid Formulations With a Low Pressure Handwand (8)	Not relevant to label uses; therefore, not assessed								
Mixing/Loading/Applying Wettable Powders With a Low Pressure Handwand (9)	Not relevant to label uses; therefore, not assessed								
Mixing/Loading/Applying Liquid With a High Pressure Handwand (10)	Not relevant to label uses; therefore, not assessed								
Mixing/Loading/Applying Liquid With a Backpack Sprayer (11)	tobacco (drench)	1.6	3.0	0.005 lb a.i./gal	40 gallons/day	0.0046	0.0000086	2,600	180,000
	tomato (greenhouse)			0.01 lb a.i./gal		0.0091	0.000017	1,300	88,000
	ornamentals			0.01 lb a.i./gal		0.0091	0.000017	1,300	88,000
	cherries			0.04 lb a.i./gal		0.037	0.000069	330	22,000
Flagger Exposures									
Flagging Aerial Spray Applications ^f (12)	clover	0.0045	0.035	0.5	350	0.011	0.000088	1,100	17,000
	tobacco			1.5	350	0.034	0.00026	360	5,700
	pecans			3.0	350	0.068	0.00053	180	2,900

Endnotes:

^a The PPE assumptions are as follows: long-sleeve shirt, long pants, chemical-resistant gloves, coveralls, chemical-resistant footwear, and organic vapor-removing cartridge respirator with approved prefilter or canister approved for pesticides.

^b Daily dermal dose (mg/kg/day) = Dermal Unit Exposure (mg/lb a.i.) x Application Rate (lb a.i./acre) x Area Treated (acres/day) x 1/(Body Weight [Kg]);

For plant dips: Daily Dermal Dose (mg/kg/day) = Dermal Unit Exposure (mg/lb a.i.) x Concentration (lb a.i./gal) x Volume Applied (gal/day) x 1/(Body Weight [Kg]).

^c Daily inhalation dose (mg/kg/day) = Inhalation Unit Exposure (µg/lb a.i.) x Application Rate (lb a.i./acre) x Area Treated (acres/day) x (1 mg/1,000 µg) x 1/(Body Weight [Kg]);

In the case of plant dips: Daily Inhalation Dose (mg/kg/day) = Inhalation Unit Exp. (µg/lb a.i.) x Concentration (lb a.i./gal) x Volume Applied (gal/day) x (1 mg/1,000 µg) x 1/(Body Weight [Kg]).

^d The short-term dermal margin-of-exposure (MOE) = 21-day dermal NOAEL (12 mg/kg/day) divided by the daily dermal dose; the target MOE is 100.

^e The short-term inhalation margin-of-exposure (MOE) = acute neurotoxicity NOAEL (1.5 mg/kg/day) divided by the daily inhalation dose; the target MOE is 100.

^f Add protective headgear for airblast application and flagging of aerial application.

Table 13. Short-Term Occupational Handler Exposures and Risks From Endosulfan With Additional PPE and Engineering Controls

Exposure Scenario (No.) [PPE/Controls]	Crop Type/Use	Dermal Unit Exposure (mg/ lb a.i.)	Inhalation Unit Exposure (µg/lb a.i.)	Application Rate (lb a.i./acre)	Area Treated per Day (acres/day)	Daily Dermal Dose ^a (mg/kg/d)	Daily Inhalation Dose ^b (mg/kg/d)	Dermal MOE ^c	Inhalation MOE ^d
<i>Mixer/Loader Exposures (Continued)</i>									
Open Mixing/Loading of Wettable Powders for Aerial Application (2a) [Water Soluble Packet]	beans	0.0067	0.024	1.0	350	0.034	0.00012	360	13,000
	sweet potatoes			2.0	350	0.067	0.00024	180	6,300
	peaches			2.5	350	0.084	0.00030	140	5,000
	small grains			0.75	600	0.043	0.00015	280	9,700
	cotton			1.5	600	0.086	0.00031	140	4,900
Open Mixing/Loading Wettable Powders for Groundboom Application (2b) [Water Soluble Packet]	beans	0.0067	0.024	1.0	80	0.0077	0.000027	1,600	55,000
	sweet potatoes			2.0	80	0.015	0.000055	780	27,000
	small grains			0.75	200	0.014	0.000051	840	29,000
	cotton			1.5	200	0.029	0.00010	420	15,000
Open Mixing/Loading Wettable Powders for Airblast Application (2c) [Water Soluble Packet]	ornamental trees/shrubs	0.0067	0.024	3.0	10	0.0029	0.000010	4,200	150,000
	hazelnuts			2.0	40	0.0077	0.000027	1,600	55,000
	peaches			2.5	40	0.0096	0.000034	1,300	44,000
Open Mixing/Loading Wettable Powders for Plants and Root Dip (2e) [Water Soluble Packet]	cherry, peach, plums	0.0067	0.024	0.05 lb a.i./gal	100 gal/day	0.00048	0.0000017	25,000	880,000

Table 13. Short-Term Occupational Handler Exposures and Risks From Endosulfan With Additional PPE and Engineering Controls (Continued)

Exposure Scenario (No.) [PPE/Controls]	Crop Type/Use	Dermal Unit Exposure (mg/ lb a.i.)	Inhalation Unit Exposure (µg/lb a.i.)	Application Rate (lb a.i./acre)	Area Treated per Day (acres/day)	Daily Dermal Dose ^a (mg/kg/d)	Daily Inhalation Dose ^b (mg/kg/d)	Dermal MOE ^c	Inhalation MOE ^d
<i>Applicator Exposures</i>									
Applying Sprays With an Airblast Sprayer (5) [Closed Cab]	ornamental trees	0.019	0.45	3.0	10	0.0081	0.00019	1,500	7,800
	hazelnuts			2.0	40	0.022	0.00051	550	2,900
	pecans			3.0	40	0.033	0.00077	370	1,900

Endnotes:

^a Daily dermal dose (mg/kg/day) = Dermal Unit Exposure (mg/lb a.i.) x Application Rate (lb a.i./acre) x Area Treated (acres/day) x 1/(Body Weight [Kg]);

For plant dips: Daily Dermal Dose (mg/kg/day) = Dermal Unit Exposure (mg/lb a.i.) x Concentration (lb a.i./gal) x Volume Applied (gal/day) x 1/(Body Weight [Kg]).

^b Daily inhalation dose (mg/kg/day) = Inhalation Unit Exposure (µg/lb a.i.) x Application Rate (lb a.i./acre) x Area Treated (acres/day) x (1 mg/1,000 µg) x 1/(Body Weight [Kg]);

In the case of plant dips: Daily Inhalation Dose (mg/kg/day) = Inhalation Unit Exp. (µg/lb a.i.) x Concentration (lb a.i./gal) x Volume Applied (gal/day) x (1 mg/1,000 µg) x 1/(Body Weight [Kg]).

^c The short-term dermal margin-of-exposure (MOE) = 21-day dermal NOEL (12 mg/kg/day) divided by the daily dermal dose; the target MOE is 100.

^d The short-term inhalation margin-of-exposure (MOE) = acute neurotoxicity NOEL (1.5 mg/kg/day) divided by the daily inhalation dose; the target MOE is 100.

E. Summary of Handler Risk Assessment

Dermal and inhalation risks for handlers (i.e., mixer/loader, applicators, and flaggers) were assessed separately because of the different route-specific endpoints and NOAELs. As noted by the USEPA (USEPA 2001a, b), handler exposures are anticipated to be short-term in nature only (i.e., 1 to 30 days per growing season). The target MOE for short-term exposures to endosulfan is 100.

(1) *Dermal exposures (short-term) and associated risks.* Dermal exposures have not been calculated for the USEPA “baseline” exposure scenarios, because these scenarios provide less clothing and personal protective equipment (PPE) than what is required by the label. The calculation of short-term dermal risks under label PPE conditions indicates that the dermal MOEs are greater than or equal to 100 for the vast majority of exposure scenarios. **The dermal MOEs are greater than or equal to 100 with label PPE** for the following scenarios:

- (Scenario 1a) Open mixing/loading of liquid formulations for aerial application to clover, tobacco, and small grains;
- (Scenario 1b) Open mixing/loading of liquid formulation for chemigation;
- (Scenario 1c) Open mixing/loading of liquids for groundboom application;
- (Scenario 1d) Open mixing/loading of liquid formulation for airblast application;
- (Scenario 1f) Open mixing/loading of liquids for plant and root dip;
- (Scenario 2c) Open mixing/loading of wettable powders for airblast application to ornamentals;
- (Scenario 2e) Open mixing/loading of wettable powders for plants and root dip;
- (Scenario 3) Applying sprays using aerial equipment;
- (Scenario 4) Applying sprays with groundboom equipment;
- (Scenario 5) Applying sprays with an airblast sprayer to ornamentals;
- (Scenario 11) Mixing/loading/applying liquids with a backpack sprayer; and
- (Scenario 12) Flagging of aerial spray operations.

The calculation of short-term dermal risks indicates that **the dermal MOEs are greater than or equal to 100 with additional PPE or engineering controls** for the following scenarios:

- (Scenario 2a) Open mixing/loading of wettable powder formulations for aerial application (water soluble packet);
- (Scenario 2b) Open mixing/loading of wettable powder formulations for groundboom application (water soluble packet);
- (Scenario 2c) Open mixing/loading of wettable powder formulations for airblast application (water soluble packet); and
- (Scenario 5) Applying sprays with airblast equipment (enclosed cab).

No additional mitigation for handlers beyond the use of water soluble packets for open mixing/loading of wettable powders and enclosed cab for airblast application are required to obtain MOEs greater than or equal to 100 for short-term dermal exposures.

(2) *Inhalation exposures (short-term) and associated risks.* Inhalation exposures have not been calculated for the USEPA “baseline” exposure scenarios, because these scenarios provide less clothing and personal protective equipment (PPE) than what is required by the label. The calculation of short-term inhalation risks under label PPE conditions indicates that the inhalation MOEs are greater than or equal to 100 for the vast majority of exposure scenarios. **The inhalation MOEs are greater than or equal to 100 with label PPE** for the following scenarios:

- (Scenario 1a) Open mixing/loading of liquid formulations for aerial application;
- (Scenario 1b) Open mixing/loading of liquid formulation for chemigation;
- (Scenario 1c) Open mixing/loading of liquid formulation for groundboom application;
- (Scenario 1d) Open mixing/loading of liquid formulation for airblast application;
- (Scenario 1f) Open mixing/loading of liquids for plant and root dip;
- (Scenario 2b) Open mixing/loading of wettable powders for groundboom application, except for cotton and tobacco;
- (Scenario 2c) Open mixing/loading of wettable powders for airblast application;
- (Scenario 2e) Open mixing/loading of wettable powders for plants and root dip;
- (Scenario 3) Applying sprays using aerial equipment;
- (Scenario 4) Applying sprays with groundboom equipment;
- (Scenario 5) Applying sprays with an airblast sprayer;
- (Scenario 11) Mixing/loading/applying liquids with a backpack sprayer; and
- (Scenario 12) Flagging of aerial spray operations.

The calculation of short-term handler inhalation risks indicates that **inhalation MOEs are greater than or equal to 100 with additional PPE or engineering controls** for the following scenarios:

- (Scenario 2a) Open mixing/loading of wettable powder formulations for aerial application (water soluble packet); and
- (Scenario 2b) Open mixing/loading of wettable powder formulations for groundboom application to cotton and tobacco (water soluble packet).

No additional mitigation for handlers beyond the use of water soluble packets is required to obtain MOEs greater than or equal to 100 for short-term inhalation exposures.

VII. POST-APPLICATION WORKER EXPOSURE/RISK ASSESSMENT

There is potential for short-term and intermediate-term post-application exposures to endosulfan for individual workers entering treated fields to conduct various work activities. Current endosulfan labels supported by the Endosulfan Task Force (ETF) indicate a restricted entry interval (REI) of 24 hours. Any worker reentering a treated field in less than 24 hours is required to wear appropriate PPE, which varies depending on the type of formulation. According to the example EC label (Phaser® 3EC), early entry into treated areas requires the wearing of coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical-resistant footwear plus socks, protective eyewear, and chemical resistant headgear if overhead contact is anticipated. According to the example WSB and WP labels (Phaser® 50WSB and Thiodan® 50WP, respectively), early entry into treated areas requires the wearing of coveralls over short-sleeved shirt and short pants, waterproof gloves⁷, footwear plus socks, protective eyewear, and chemical resistant headgear if overhead contact is anticipated.

For the purpose of conducting the worker post-application (reentry) assessment, crop groupings were matched with dislodgeable foliar residue (DFR) data in a manner similar to that in the revised EPA occupational exposure assessment (USEPA 2001a). DFR data are available from a study on endosulfan (MRID No. 44031-02). HED has recommended that the data from this study be used in assessing post-application exposures from agricultural activities involving endosulfan, and the Agency has used this same study in the revised occupational exposure assessment (USEPA 2001a). DFR data for peaches were used to represent tree crops; specifically, DFR data based on the application rate of 3 lb a.i./acre were used. DFR data for grapes at an application rate of 1.5 lbs a.i./acre were used for assessment of exposures associated with various activities in grapes (e.g., grape harvesting, girdling, and irrigating). DFR data for melons, reflecting an application rate of 1 lb a.i./acre, were used to estimate exposures for a variety of activities relating to field crops.

F. Summary of Dislodgeable Foliar Residue (DFR) Data

(1). *Overview.* A dissipation study for foliar dislodgeable residues of endosulfan associated with use of Phaser® 3EC and Phaser® 50WSB on melons, peaches, and grapes (AgrEvo 1997) has been submitted to the Agency (MRID No. 444031-02). In this study, the test substance consisting of the end use products was applied twice at one-week intervals in the case of melons and grapes, and once on peaches at a site in California. The use rate for each application was in all cases 1 lb a.i./acre for melons, 1.5 lb a.i./acre for grapes and 3 lb a.i./acre for peaches. The three crops were maintained using standard methods, which included supplemental moisture by furrow irrigation. Foliar samples were collected at 0, 1, 3, 5, and 7 days after the first application, and 0, 1, 3, 5, 7, 10, 14, 17, 21, 24, and 28 days after the second application. Duplicate leaf samples consisted of 5 cm² punches of untreated (control) foliage and composited 5 cm² punches of treated

⁷ For contact with dried water-based solutions of wettable powder, waterproof gloves are in effect a chemical-resistant barrier.

foliage representing a total of 200 cm² of total leaf surface area. Endosulfan residues were dislodged from the leaf samples with 3 washes containing 50 ml of 0.012 percent Aerosol OT. Analytes were extracted from the pooled dislodging solution using 100 ml hexane. The detected amounts of residue are shown in Table 14.

(2). *Form of the DFR Dissipation Curves*. Despite (1) clear evidence in the DFR study (Agrevo 1997) that the DFR dissipation data are biphasic for both the EC and WP formulations, and (2) demonstration of significantly higher foliar residues for the WP formulation compared to the EC formulation, the Agency chose to use a log-linear fit of the data across the entire time frame of dissipation for the WP formulation to represent both formulation types in the its assessment of occupational post-application exposures (USEPA 2000c). In the revised HED assessment (USEPA 2001a), the Agency has correctly taken a formulation-specific approach to assessing post-application occupational exposures, making use of the formulation-specific DFR monitoring data by Agrevo (1997) [MRID No. 444031-02]. These data are provided in Table 14. However, the DFR study report submitted by the registrant indicates that relatively mediocre correlation coefficients (for example, 0.71 for peaches, 0.52 for grapes, and 0.76 for melons for the EC formulation) were obtained when the data were fit to a single log-linear line across the entire time-frame of the DFR data. This suggests that an adequate fit is not obtained using a simple log-linear fit across the entire dissipation period.

If data are plotted in a log-linear fashion (i.e., \ln [DFR] vs. time), the biphasic nature of the dissipation curve is readily apparent. With a compound like endosulfan, there is a distinct initial rapid decline phase (“Phase 1”), possibly representing transformation processes on the surface of the leaves, followed by a much slower decline phase (“Phase 2”), possibly representing uptake by the plant or slower transformation processes. For example, if the data for the EC or WP formulation from the study report are plotted as (\ln [DFR]) vs. time (i.e., in log-linear form), the data suggest a “hockey stick” type of plot rather than a single straight line plot. This type of behavior may also be explained, in part, by the presence of the 2 isomers of endosulfan (α and β) which may have different rates for different dissipation processes (e.g., volatilization).

Table 14. Measured Dislodgeable Foliar Residues of Endosulfan in Melons, Peaches, and Grapes

Application	Days Post-Application	Dislodgeable Foliar Residues (DFRs) ^a ($\mu\text{g}/\text{cm}^2$)					
		Melons		Peaches ^b		Grapes	
		EC	WP	EC	WP	EC	WP
1	0	0.70	1.77	---	---	0.61	1.51
	1	0.21	0.72	---	---	0.26	0.90
	3	0.05	0.22	---	---	0.08	0.61
	5	0.05	0.19	---	---	0.06	0.39
	7	0.04	0.11	---	---	0.04	0.29
2	0	1.23	1.00	0.46	1.02	0.71	1.32
	1	0.54	1.14	0.16	0.55	0.31	1.36
	3	0.15	0.53	0.09	0.43	0.11	0.51
	5	0.09	0.32	0.07	0.30	0.09	0.74
	7	0.06	0.18	0.04	0.22	0.03	0.28
	10	0.05	0.12	0.03	0.16	0.02	0.20
	14	0.05	0.07	0.03	0.11	0.04	0.24
	17	0.03	0.04	0.03	0.10	0.05	0.30
	21	0.02	0.02	0.05	0.09	0.02	0.20
	24	0.02	0.04	0.02	0.07	0.04	0.19
	28	0.02	0.03	0.01	0.04	< 0.01 ^c	0.13

^a DFR residues from crops resulting from application of Phaser[®]EC or Phaser[®]WP; residue values shown are averages of triplicate sample taken at each sample interval.

^b Peaches received only one application of test formulation.

^c DFR value is below the limit of quantification ($0.01\mu\text{g}/\text{cm}^2$).

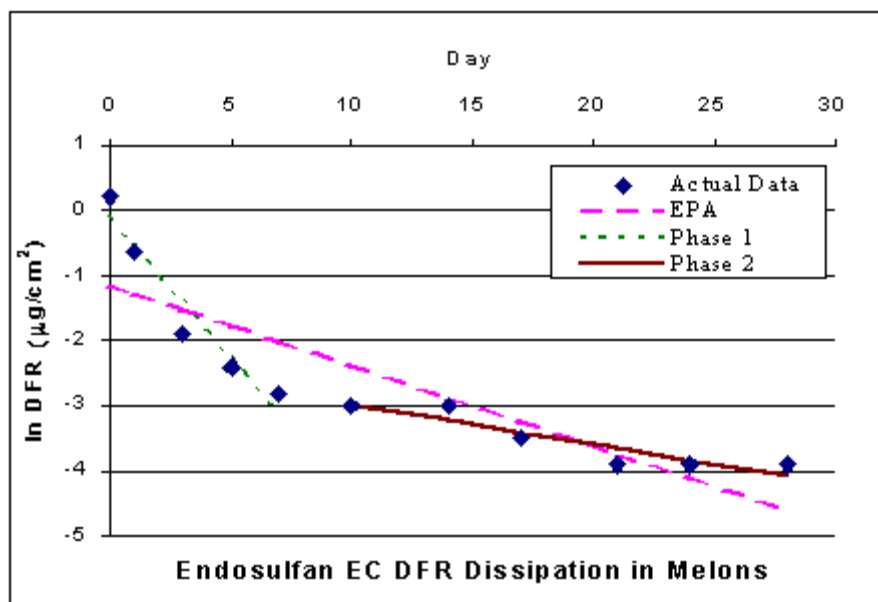
The biphasic plot for endosulfan DFR dissipation on melon foliage has a Phase 1 half-life ($t_{1/2}$) of 0.7 days and a Phase 2 half-life of 8.6 days for the EC formulation (see Figure 1). Across the three crop types studied (melons, peaches, and grapes), the Phase 1 half-life is more than one order of magnitude shorter than the Phase 2 half-life for a given crop/formulation type combination. Interestingly, the Phase 1 half-life is longer for the WP formulation by about a factor of 3 compared to the Phase 1 half-life for the EC formulation in the case of 2 of the crop types (melons and grapes). The breakpoint between the 2 phases appears to be approximately Day 7 post-application for the EC formulation, and Day 10 post-application for the WP formulation. These estimated half-life data are shown below in Table 15.

The degree of divergence of the Agency's predictive model (based on a log-linear fit across the entire residue dissipation time frame) from the measured endosulfan DFR values for Phaser WP can be observed when one examines Table 11 from the HED document (USEPA, 2000a) to the measured values from the DFR study. For example, the DFR value estimated by the Agency for endosulfan WP on melons in California was 0.70 ug/cm² on day 0 while the measured DFR was 1.0 ug/cm² (a biphasic approach predicts a value of 1.1 ug/cm²). The DFR value estimated by the Agency on day 10 was 0.18 ug/cm², but the measured DFR was 0.12 ug/cm² (a biphasic approach predicts a value of 0.10 ug/cm²). Much of the error in the Agency's estimating $t_{1/2}$ with a single log-linear fit occurred in Phase 1, which happens to be the critical time for estimating most REIs. The implications for accurate estimation of REIs are significant.

Table 15. Half-Life Estimates Based on Biphasic (2-Compartment) Kinetics (Agrevo 1997)

Formulation Type	Crop	Foliar Dissipation Half-Life (Days)	
		Rapid-Phase (Phase 1)	Slow-Phase (Phase 2)
EC	Melons	0.7	8.6
	Peaches	0.4	10.5
	Grapes	0.7	11.1
WP	Melons	2.9	2,240
	Peaches	0.3	6.2
	Grapes	2.5	84.8

Figure 1. Regression of Endosulfan Melon DFR Data on Time for EC Formulation



(3) *Regression Analysis of the Formulation-Specific DFR Data.* For the purposes of this assessment, a regression analysis was conducted using the natural log-transformed DFR data and

biphasic kinetics, based on the apparent “break-points” in the curves representing the shift from the initial rapid phase (Phase 1) to the more gradual dissipation phase (Phase 2). To capture the initial phase (Phase 1), the natural log-transformed DFR data for Days 0 through 7 following the last application of the EC formulation, or Days 0 through 10 in the case of the WP formulation, were input into Microsoft Excel® to obtain the linear regression parameters for the equation $y = mx + b$, where:

y	=	the natural log of the DFR value on Day x
x	=	the number of days post-application
m	=	the slope of the regression line
b	=	constant

To capture the second phase (Phase 2), the natural log-transformed DFR data for Days 8 through 28 following the last application of EC formulation, or Days 11 through 28 for the WP formulation, were input into Microsoft Excel® to obtain the linear regression parameters. The regression parameters are shown below in Table 16 for the following cases: (1) Case I: log-linear fit across all data points (i.e., identical to the Agency’s approach); (2) Case II: Phase 1 of biphasic kinetics including data for Days 0 through 7; (3) Case III: Phase 2 of biphasic kinetics including data for Days 8 through 28; (4) Case IV: Phase 1 of biphasic kinetics including data for Days 0 through 10; and (5) Case V: Phase 2 of biphasic kinetics including data for Days 11 through 28. Plots of the formulation-specific/crop-specific dissipation curves for Cases I, II, and III for the EC formulation and for Cases I, IV, and V for the WP formulation are shown in Attachment B. The results for each formulation type/crop types combination are summarized and interpreted below.

Peaches - Dislodgeable endosulfan residues were generally higher on WP-treated foliage than on EC-treated foliage, although the rates of dissipation were very similar. The mean residues found on Day 0 after application for the EC and WP formulations were 0.46 µg/cm² and 1.02 µg/cm², respectively. By Day 21, the dislodgeable residues of endosulfan on the foliage had reduced to 0.05 µg/cm² and 0.09 µg/cm² for the EC and WP formulations, respectively. When a linear regression was performed on the natural log-transformed DFR data over the entire time course of the dissipation (i.e., Days 0 through 28) for Phaser® EC, slope (m) is -0.09131 and the y-intercept (b) is -1.91431. When the biphasic kinetics are accounted for, and the natural log-transformed DFR data for Days 0 through 7 are input into a linear regression, the slope and intercept for Phase 1 are -0.30548 and -1.20145, respectively. As indicated by the r² value of 0.88694, consideration of the biphasic kinetics for Days 0 through 7 provides a better fit of the data than either (1) the simple linear regression across all the data points; or (2) fitting of the Phase 1 data based on Days 0 through 10, which may take the curve past the break point of Phase 1 and Phase 2. When a linear regression was performed on the natural log-transformed DFR data over the entire time course of the dissipation (i.e., Days 0 through 28) for Phaser® WP, the slope

Table 16. Regression Parameters for 5 Cases for Fitting the Endosulfan DFR Data

Formulation Type	Crop	Regression Parameter ^a	Case Description for Regression of Endosulfan DFR Data ^b				
			Case I	Case II	Case III	Case IV	Case V
EC	Melons	Slope	-0.12341	-0.42539	-0.062000	-0.31398	-0.06329
		Intercept	-1.15627	-0.14429	-2.3611	-0.39332	-2.33132
		r^2	0.760823	0.927099	0.838204	0.852126	0.751366
	Peaches	Slope	-0.09131	-0.30549	-0.04951	-0.24593	-0.07415
		Intercept	-1.91431	-1.20145	-2.73132	-1.3346	-2.16294
		r^2	0.707732	0.88694	0.367451	0.876897	0.470485
	Grapes	Slope	-0.10238	-0.41296	-0.03669	-0.34757	-0.08932
		Intercept	-1.65347	-0.60561	-2.94675	-0.75179	-1.73238
		r^2	0.620471	0.950206	0.160114	0.939717	0.555678
WP	Melons	Slope	-0.13955	-0.26611	-0.07573	-0.23744	-0.04898
		Intercept	-0.35023	0.179945	-1.66707	0.115856	-2.28424
		r^2	0.883775	0.966314	0.628731	0.968481	0.35041
	Peaches	Slope	-0.09728	-0.19818	-0.06794	-0.17093	-0.06847
		Intercept	-0.55653	-0.19386	-1.14718	-0.25477	-1.13506
		r^2	0.925047	0.930679	0.92514	0.936614	0.875184
	Grapes	Slope	-0.07169	-0.20761	-0.02662	-0.1969	-0.04924
		Intercept	-0.17214	0.33188	-1.08607	0.307953	-0.56415
		r^2	0.739024	0.792659	0.40595	0.880108	0.776054

^a Regression parameters for linear regression of natural log-transformed DFR data with number of days following application.

^b Description of Cases: Case I = linear regression across all data points, Days 0 through 28 (USEPA approach).
Case II = linear regression across first phase of biphasic kinetics, Days 0 through 7.
Case III = linear regression across second phase of biphasic kinetics, Days 8 through 28.
Case IV = linear regression across first phase of biphasic kinetics, Days 0 through 10.
Case V = linear regression across second phase of biphasic kinetics, Days 11 through 28.

(m) is -0.09728 and the y-intercept (b) is -0.55653. When the biphasic kinetics are accounted for, and the natural log-transformed DFR data for Days 0 through 10 are input into a linear regression, the slope and intercept for Phase 1 are -0.17093 and -0.25477. This provides the highest r^2 value of 0.936614. Thus, consideration of the biphasic kinetics for Days 0 through 10 provides a better fit of the data for the WP formulation than either (1) the simple linear regression across all the data points; or (2) fitting of the Phase 1 data based on Days 0 through 7.

Grapes - As with peaches, dislodgeable endosulfan residues were generally higher on WP-treated foliage than on EC-treated foliage, although the rates of dissipation were not as similar as with peaches. The mean residues found on Day 0 after application for the EC and WP formulations were 0.71 $\mu\text{g}/\text{cm}^2$ and 1.32 $\mu\text{g}/\text{cm}^2$, respectively. By Day 21 after the second application, the dislodgeable residues of endosulfan on the foliage had reduced to 0.02 $\mu\text{g}/\text{cm}^2$ and 0.20 $\mu\text{g}/\text{cm}^2$ for the EC and WP formulations, respectively. When a linear regression was performed on the natural log-transformed DFR data over the entire time course of the dissipation (i.e., Days 0 through 28) for Phaser[®] EC, the slope (m) is -0.10238, the y-intercept (b) is -1.65347, and the r^2 value is 0.620471. When the biphasic kinetics are accounted for, and the natural log-transformed DFR data for Days 0 through 7 are input into a linear regression, the slope and intercept for Phase 1 are -0.41296 and -0.60561, respectively. As indicated by the r^2 value of 0.950206, consideration of the biphasic kinetics for Days 0 through 7 provides a better fit of the data than either (1) the simple linear regression across all the data points; or (2) fitting of the Phase 1 data based on Days 0 through 10, which may take the curve past the break point of Phase 1 and Phase 2. When a linear regression was performed on the natural log-transformed DFR data over the entire time course of the dissipation (i.e., Days 0 through 28) for Phaser[®] WP, the slope (m) is -0.07169, the y-intercept (b) is -0.17214, and the r^2 value is 0.739024. When the biphasic kinetics are accounted for, and the natural log-transformed DFR data for Days 0 through 10 are input into a linear regression, the slope and intercept for Phase 1 for the WP formulation are -0.1969 and 0.307953, respectively. This approach provides the highest r^2 value of 0.880108. Thus, consideration of the biphasic kinetics for Days 0 through 10 provides a better fit of the data for the WP formulation than either (1) the simple linear regression across all the data points; or (2) fitting of the Phase 1 data based on Days 0 through 7.

Melons - As with peaches and grapes, dislodgeable endosulfan residues were generally higher on WP-treated foliage than on EC-treated foliage. The mean residues found on Day 0 after application for the EC and WP formulations were 1.23 $\mu\text{g}/\text{cm}^2$ and 1.00 $\mu\text{g}/\text{cm}^2$, respectively. This is the only day on which the DFR value for the EC-treated foliage exceeds that for the WP-treated foliage, and may represent a measurement anomaly. By Day 21 after the second application, the dislodgeable residues of endosulfan on the melon foliage had reduced to 0.02 $\mu\text{g}/\text{cm}^2$ for both formulation types. When a linear regression was performed on the natural log-transformed DFR data over the entire time course of the dissipation (i.e., Days 0 through 28) for Phaser[®] EC, the slope (m) is -0.12341, the y-intercept (b) is -1.15627, and the r^2 value is 0.760823. When the biphasic kinetics are accounted for, and the natural log-transformed DFR data for Days 0 through 7 are input into a linear regression, the slope and intercept for Phase 1 are -0.42539 and -0.14429, respectively. As indicated by the r^2 value of 0.927099, consideration of the biphasic kinetics for Days 0 through 7 provides a better fit of the data for the EC formulation than either (1) the simple linear regression across all the data points; or (2) fitting of the Phase 1 data based on Days 0 through 10, which may

take the curve past the break point of Phase 1 and Phase 2. With regard to Phaser® WP, when a linear regression was performed on the natural log-transformed melon DFR data over the entire time course of the dissipation (i.e., Days 0 through 28), the slope (m) is -0.13955, the y-intercept (b) is -0.35023, and the r^2 value is 0.883775. When the biphasic kinetics are accounted for, and the natural log-transformed DFR data for Days 0 through 10 are input into a linear regression, the slope and intercept for Phase 1 for the WP formulation are -0.23744 and 0.115856, respectively. This approach provides the highest r^2 value of 0.968481.

(4) *Predicted Daily DFR Levels Based on Biphasic Kinetics.* Using the most appropriate regression equations, the predicted daily DFRs on foliage on Days 1 through 41 in the case of peaches, melons, grapes are shown in Tables 17 and 18 for the EC and WP formulations, respectively. The DFR studies on peaches, grapes, and melons were conducted at application rates of 3 lb a.i./acre, 1.5 lb a.i./acre, and 1.0 lb a.i./acre, respectively, and the DFR data reflect these use rates. The following regression equations were used describe the predicted endosulfan residues for the EC formulation:

- Peaches, Phase 1: $\ln(\text{DFR}_p) = (-0.30549 * t) - 1.20145$ [$r^2 = 0.88694$]
- Peaches, Phase 2: $\ln(\text{DFR}_p) = (-0.04951 * t) - 2.73132$ [$r^2 = 0.367451$]
- Melons, Phase 1: $\ln(\text{DFR}_p) = (-0.42539 * t) - 0.14429$ [$r^2 = 0.927099$]
- Melons, Phase 2: $\ln(\text{DFR}_p) = (-0.06200 * t) - 2.3611$ [$r^2 = 0.838204$]
- Grapes, Phase 1: $\ln(\text{DFR}_p) = (-0.41296 * t) - 0.60561$ [$r^2 = 0.950206$]
- Grapes, Phase 2: $\ln(\text{DFR}_p) = (-0.03669 * t) - 2.94675$ [$r^2 = 0.160114$]

The following regression equations were used to describe the predicted endosulfan residues for the WP formulation:

- Peaches, Phase 1: $\ln(\text{DFR}_p) = (-0.17093 * t) - 0.25477$ [$r^2 = 0.936614$]
- Peaches, Phase 2: $\ln(\text{DFR}_p) = (-0.06847 * t) - 1.13506$ [$r^2 = 0.875184$]
- Melons, Phase 1: $\ln(\text{DFR}_p) = (-0.23744 * t) + 0.11586$ [$r^2 = 0.968481$]
- Melons, Phase 2: $\ln(\text{DFR}_p) = (-0.04898 * t) - 2.28424$ [$r^2 = 0.35041$]
- Grapes, Phase 1: $\ln(\text{DFR}_p) = (-0.1969 * t) + 0.307953$ [$r^2 = 0.880108$]
- Grapes, Phase 2: $\ln(\text{DFR}_p) = (-0.04924 * t) - 0.56416$ [$r^2 = 0.776054$].

Table 17. Predicted DFR Levels ($\mu\text{g}/\text{cm}^2$) Based on Regression Equations for Phaser® EC

Sample Interval ^a	Predicted DFR - Biphasic Kinetics ^b			Sample Interval ^a	Predicted DFR -Biphasic Kinetics ^b		
	Grapes	Peaches	Melons		Grapes	Peaches	Melons
0	0.55	0.30	0.87	21	0.024	0.023	0.026
1	0.36	0.22	0.57	22	0.023	0.022	0.024
2	0.24	0.16	0.37	23	0.023	0.021	0.023
3	0.16	0.12	0.24	24	0.022	0.020	0.021
4	0.10	0.089	0.16	25	0.021	0.019	0.020
5	0.069	0.065	0.10	26	0.020	0.018	0.019
6	0.046	0.048	0.067	27	0.019	0.017	0.018
7	0.030	0.035	0.044	28	0.019	0.016	0.017
8	0.039	0.044	0.057	29	0.018	0.015	0.016
9	0.038	0.042	0.054	30	0.017	0.015	0.015
10	0.036	0.040	0.051	31	0.017	0.014	0.014
11	0.035	0.038	0.048	32	0.016	0.013	0.013
12	0.034	0.036	0.045	33	0.016	0.013	0.012
13	0.033	0.034	0.042	34	0.015	0.012	0.011
14	0.031	0.033	0.040	35	0.015	0.012	0.011
15	0.030	0.031	0.037	36	0.014	0.011	0.010
16	0.029	0.029	0.035	37	0.014	0.010	0.0095
17	0.028	0.028	0.033	38	0.013	0.0099	0.0089
18	0.027	0.027	0.031	39	0.013	0.0094	0.0084
19	0.026	0.025	0.029	40	0.012	0.0090	0.0079
20	0.025	0.024	0.027	41	0.012	0.0086	0.0074

^a Days after treatment

^b Based on the following regression equations:

For grapes, $\ln(\text{DFR}_p) = (-0.41296 * t) - 0.60561$ [$r^2 = 0.950206$] for Days 0 through 7 (Phase 1)

and $\ln(\text{DFR}_p) = (-0.03669 * t) - 2.94675$ [$r^2 = 0.160114$] Days 8 through 41 (Phase 2).

For peaches, $\ln(\text{DFR}_p) = (-0.30549 * t) - 1.20145$ [$r^2 = 0.88694$] for Days 0 through 7 (Phase 1)

and $\ln(\text{DFR}_p) = (-0.04951 * t) - 2.73132$ [$r^2 = 0.367451$] for Days 8 through 41 (Phase 2).

For melons, $\ln(\text{DFR}_p) = (-0.42539 * t) - 0.14429$ [$r^2 = 0.927099$] for Days 0 through 7 (Phase 1)

and $\ln(\text{DFR}_p) = (-0.06200 * t) - 2.361$ [$r^2 = 0.838204$] for Days 8 through 41 (Phase 2).

Table 18. Predicted DFR Levels ($\mu\text{g}/\text{cm}^2$) Based on Regression Equations for Phaser® WP

Sample Interval ^a	Predicted DFR - Biphasic Kinetics ^b			Sample Interval ^a	Predicted DFR -Biphasic Kinetics ^b		
	Grapes	Peaches	Melons		Grapes	Peaches	Melons
0	1.36	0.78	1.12	21	0.20	0.076	0.036
1	1.12	0.65	0.89	22	0.19	0.071	0.035
2	0.92	0.55	0.70	23	0.18	0.067	0.033
3	0.75	0.46	0.55	24	0.17	0.062	0.031
4	0.62	0.39	0.43	25	0.17	0.058	0.030
5	0.51	0.33	0.34	26	0.16	0.054	0.029
6	0.42	0.28	0.27	27	0.15	0.051	0.027
7	0.34	0.23	0.21	28	0.14	0.047	0.026
8	0.28	0.20	0.17	29	0.14	0.044	0.025
9	0.23	0.17	0.13	30	0.13	0.041	0.023
10	0.19	0.14	0.10	31	0.12	0.038	0.022
11	0.33	0.15	0.059	32	0.12	0.036	0.021
12	0.32	0.14	0.057	33	0.11	0.034	0.020
13	0.30	0.13	0.054	34	0.11	0.031	0.019
14	0.29	0.12	0.051	35	0.10	0.029	0.018
15	0.27	0.12	0.049	36	0.097	0.027	0.017
16	0.26	0.11	0.047	37	0.092	0.026	0.017
17	0.25	0.10	0.044	38	0.088	0.024	0.016
18	0.23	0.094	0.042	39	0.083	0.022	0.015
19	0.22	0.088	0.040	40	0.079	0.021	0.014
20	0.21	0.082	0.038	41	0.076	0.019	0.014

^a Days after treatment

^b Based on the following regression equations:

For grapes, $\ln(\text{DFR}_p) = (-0.1969 * t) + 0.307953$ [$r^2 = 0.880108$] for Days 0 through 10 (Phase 1)
and $\ln(\text{DFR}_p) = (-0.04924 * t) - 0.56416$ [$r^2 = 0.776054$] for Days 11 through 41 (Phase 2).
For peaches, $\ln(\text{DFR}_p) = (-0.17093 * t) - 0.25477$ [$r^2 = 0.936614$] for Days 0 through 10 (Phase 1)
and $\ln(\text{DFR}_p) = (-0.06847 * t) - 1.13506$ [$r^2 = 0.875184$] for Days 11 through 41 (Phase 2).
For melons, $\ln(\text{DFR}_p) = (-0.23744 * t) + 0.115856$ [$r^2 = 0.968481$] for Days 0 through 10 (Phase 1)
and $\ln(\text{DFR}_p) = (-0.04898 * t) - 2.28424$ [$r^2 = 0.35041$] for Days 11 through 41 (Phase 2).

B. SUMMARY OF TRANSFER COEFFICIENTS

The transfer coefficient is the conceptual term that links dislodgeable foliar residues (DFRs) to worker reentry exposures. The transfer coefficient for dermal exposure is directly related to the degree of contact between the crop and worker (which is dependent upon the height and density of foliage) and the nature of the worker contact(s) for specific work activities (e.g., weeding, pruning, cutting, sorting/bundling, harvesting). The transfer coefficient (TC) can be thought of as the surface area of treated foliage contacted by the worker per hour. Thus, the TC is work task-specific and crop-specific (or crop cluster-specific). The transfer coefficient (TC) is calculated as follows:

$$TC (cm^2/hr) = [Exposure (\mu g/hr)]/[DFR (\mu g/cm^2)] \quad [1]$$

The Agricultural Reentry Task Force (ARTF) has carried out a number of field studies for various worker reentry activities in different crops to empirically determine the appropriate transfer coefficients. The ARTF has also been able to group various crops and activities according to potential dermal exposure (low, medium, high) when consideration is given to correlated variables such as crop height and extent of foliage. For example, based on this grouping exercise, the ARTF has placed harvesting melons in a low exposure cluster. Thus, crops were grouped according to similar application rates, transfer coefficients, and DFR data used. Because the Endosulfan Task Force (ETF) member companies are also members of the ARTF, the ETF has chosen to cite and utilize TC data from the ARTF in this assessment.

In the revised HED occupational assessment on endosulfan (USEPA 2001a), the Agency has used transfer coefficients from the ARTF database. We agree with the Agency that because the ARTF data are available to be used in this assessment of endosulfan, the ARTF transfer coefficient values are more appropriate than the USEPA default values used in the earlier USEPA occupational exposure assessment (USEPA 2000c), which were based on an earlier policy memo (USEPA 1998b). The specific transfer coefficients selected by the Agency were developed by HED's Sciences Advisory Council for Exposure using the ARTF database, as described in USEPA Policy Memo No. 3.1 (USEPA 2000a). For the purpose of this assessment, we adopt the same TC values here, recognizing that some of the selected TC values represent the "high end" of the range for a given crop/work activity combination. Thus, the reentry exposures calculated here are likely to exceed actual central tendency values of exposures.

C. WORKER REENTRY EXPOSURE SCENARIOS AND ASSUMPTIONS

Short-term and intermediate-term daily exposures were calculated to allow comparison to the daily exposures estimated by the Agency. The Endosulfan Task Force (ETF) agrees with the Agency that there are potential short-term and intermediate-term post-application exposures related to a variety of activities for workers entering treated fields. The worker exposure scenarios addressed in this assessment are summarized in Table 19, along with the selected transfer coefficients.

Because of the multitude of crops potentially treated with EC and WP formulations

containing endosulfan, indicator crops/activities, application rate assumptions, and example transfer coefficients were used that are likely to be representative for post-application worker reentry exposures to endosulfan. The crop groups/activities assessed were selected because applicable residue data were available (see description of the relevant post-application dislodgeable foliar residue (DFR) study [MRID No. 444031-02] above); these are the same activity categories assumed by the Agency, and appropriate transfer coefficient data from the ARTF efforts were available.

D. ESTIMATION OF SHORT-TERM POST-APPLICATION WORKER EXPOSURES TO ENDOSULFAN

It is anticipated that workers may receive short-term (1 to 30 days) post-application exposures during reentering treated growing areas to conduct various work activities. The assumptions and equations used to estimate exposures and MOEs are noted below.

(1) Assumptions. A number of assumptions were made in conducting the short-term post-application worker exposure and risk assessment. These include:

- The maximum transfer coefficient for each crop category per USEPA HED Policy Memo No. 3.1 (USEPA 2000a), which utilizes the ARTF database;
- Daily post-application DFR values based on biphasic dissipation kinetics;
- Maximum indicated label use rates for assessing short-term exposures;
- Exposure duration is assumed to be 8 hours per day, representing a typical work day;
- An average body weight of 70 kg; and
- A dermal NOAEL of 12 mg/kg/day based is the most appropriate toxicological benchmark.

(2) Exposure calculations. The predicted DFR values (DFR_p) based on the biphasic regression equations were adjusted to reflect actual crop-specific label maximum application rates for the WP and EC formulations, using the following equation:

$$DFR_a(\mu g/cm^2) = \frac{Study\ DFR_p(\mu g/cm^2) \times Label\ Maximum\ Crop\ Application\ Rate\ (lb\ a.i./acre)}{Study\ Application\ Rate\ (lb\ a.i./acre)}$$

Table 19. ARTF Transfer Coefficients Used in Assessing Post-Application Occupational Exposures to Endosulfan

Crop Category	Crop	Worker Activity	Transfer Coefficient (cm²/hr)
Grapes	Table grapes/raisins	Cane turning, tying, girdling	10,000
	Juice grapes	Tying, training, hand harvesting, hand pruning, thinning	5,000
	Grapes (all)	Scouting, irrigation	1,000
Tree Crops	Apple, apricot, cherry, nectarine, peach, pear, plum, prune, Christmas trees	Thinning, staking, topping, training, hand harvesting	8,000
	Ornamental trees/shrubs including evergreen trees and non-bearing citrus	Hand pruning, seed cone harvesting	3,000
	Apple, apricot, cherry, nectarine, peach, pear, plum, prune, ornamental trees and shrubs, including evergreens, non-bearing citrus, and Christmas trees	Irrigating and scouting	1,000
	Macadamia nuts and pecans	Hand harvesting, pruning, thinning	2,500
		Irrigating, scouting	500
	Hazelnut, almonds, walnut	Hand harvesting, pruning	2,500
		Irrigating/scouting	500
Field Crops	Blueberries, kohlrabi, broccoli, cabbage	Hand harvesting, pruning, thinning, irrigating	5,000
	Kohlrabi, broccoli, cabbage	Irrigating, scouting	4,000
	Blueberries	Irrigating, scouting	1,000
	Brussel sprouts, cauliflower	Topping, irrigating, hand harvesting, tying	5,000
		Irrigating, scouting	4,000
	Corn	Detasseling	17,000
		Irrigating, scouting	1,000
	Cucumbers, melons, pumpkin, squash, beans, peas, celery, lettuce, spinach, carrots	Hand harvesting, pruning, thinning, turning, leaf pulling	2,500
	Alfalfa, barley, clover, oats, rye, wheat, white potatoes, cucumber, melons, pumpkin, squash, beans, peas, celery, lettuce, spinach	Irrigating, scouting	1,500
	Carrots	Irrigating, scouting	300
	Pepper, eggplant, tomato	Hand harvesting, staking, tying, pruning, thinning, training	1,000
		Irrigating, scouting	700
	Pineapple	Hand harvesting	1,000
		Irrigating, scouting	500
	Strawberry	Hand harvesting, pinching, pruning, training	1,500
		Irrigating, scouting	400

Table 19. ARTF Transfer Coefficients Used Assessing Post-Application Occupational Exposures to Endosulfan (Continued)

Crop Category	Crop	Worker Activity	Transfer Coefficient (cm ² /hr)
Field Crops (cont'd.)	Cotton, collard greens, kale, mustard greens, sweet potatoes, radish, rutabaga, turnip	Hand harvesting, pruning, thinning	2,500
	Cotton, collard greens, kale, mustard greens, sweet potatoes	Irrigating, scouting	1,500
	Radishes, rutabaga, turnip	Irrigating, scouting	300
	Tobacco	Hand harvesting, pruning, striping, thinning, topping, hand weeding	2,000
		Irrigating, scouting	1,300

Short-term daily doses were calculated as follows based on the adjusted DFR data.

$$ADD = [DFR_a \times TC \times ET \times (mg/1,000 \mu g)]/BW$$

where,

ADD = per-event average daily dose (mg/kg/day)

DFR_a = adjusted dislodgeable foliar residue value (μg/cm²)

TC = transfer coefficient for specific work activity (cm²/hr)

ET = exposure duration (8 hr/day)

BW = body weight (70 kg).

The estimated short-term exposures on key days of reentry are shown in Table 20.

(3) Calculation of short-term post-application risks. The Margin-of-Exposure (MOE) is calculated for each day post-application, based on the biphasic dissipation curves until the target MOE for each crop/formulation/work activity combination is attained. The equation for calculation of the MOE is as follows:

$$MOE = NOAEL/ADD$$

where,

MOE = margin of exposure (unitless)

NOAEL = No-Observed-Adverse-Effect-Level

ADD = per-event average daily dose (mg/kg/day)

For assessment of short-term post-application worker risks, the target MOE is 100 and the NOAEL is 12 mg/kg/day based on the available dermal exposure studies described previously.

Table 20. Short-Term Occupational Post-Application Exposures to Endosulfan: Associated Margins of Safety

Crop ^a	Maximum Label Application Rate (lb. a.i./acre) ^d		Transfer Coefficient (cm ² /hr) ^e	Work Activity ^f	Surrogate Crop for DFR Data ^g	DAT ^h	DFR _a (µg/cm ²) ⁱ		MOE ^j	
	WP ^b	EC ^e					WP	EC	WP	EC
Table Grapes/Raisins	1.5	1.5	10,000	Cane turning and tying, girdling	Grapes	0	1.36	0.55	8	19
						4	0.62	0.10	17	100
						35	0.10	NA	100	NA
Juice Grapes	1.5	1.5	5,000	Tying, training, hand harvesting, hand pruning, thinning	Grapes	0	1.36	0.55	15	38
						3	0.75	0.16	28	130
						10	0.19	NA	110	NA
Grapes (Table/Raisin and Juice)	1.5	1.5	1,000	Scouting and irrigating	Grapes	0	1.36	0.55	77	190
						2	0.92	NA	110	NA
Apple, Apricot, Cherry, Nectarine, Peach, Pear, Plum, Prune	2.5	2.5	8,000	Thinning, staking, topping, training, hand harvesting	Peaches	0	0.65	0.25	20	53
						3	0.39	0.10	34	130
						10	0.12	NA	110	NA
			1,000	Irrigating and scouting	Peaches	0	0.65	0.25	160	420
Ornamental Trees/Shrubs, Including Evergreen Trees and Non-Bearing Citrus	3	3	3,000	Hand pruning and seed cone harvesting	Peaches	0	0.78	0.30	45	120
						5	0.33	NA	110	NA
			1,000	Irrigating and scouting	Peaches	0	0.78	0.30	140	350
Macadamia Nuts and Pecans	2.5	2.5	2,500	Hand harvesting, pruning, thinning	Peaches	0	0.78	0.30	54	140
						4	0.39	NA	110	NA
			500	Irrigating and scouting	Peaches	0	0.78	0.30	270	700
Clover	0.5	0.5	1,500	Irrigating and scouting	Melons	0	0.56	0.43	120	160
Small Grains (Barley, Oats, Rye, Wheat)	0.75	0.75	1,500	Irrigating and scouting	Melons	0	0.84	0.65	83	110
						1	0.66	NA	110	NA

Table 20. Short-Term Occupational Post-Application Exposures to Endosulfan: Associated Margins of Safety (Continued)

Crop ^a	Maximum Label Application Rate (lb. a.i./acre) ^d		Transfer Coefficient (cm ² /hr) ^e	Work Activity ^f	Surrogate Crop for DFR Data ^g	DAT ^h	DFR _a (µg/cm ²) ⁱ		MOE ^j	
	WP ^b	EC ^c					WP	EC	WP	EC
Hazelnuts, Almonds, Walnuts	2	2	2,500	Hand harvesting and pruning	Peaches	0	0.52	0.20	81	210
						2	0.37	NA	110	NA
			500	Irrigating and scouting	Peaches	0	0.52	0.20	410	1,000
Broccoli, Cabbage (edible crop)	1	1	5,000	Hand harvesting, pruning, and thinning	Melons	0	1.12	0.87	19	24
						4	0.43	0.16	48	130
						8	0.17	NA	120	NA
	1	1	4,000	Irrigating and scouting	Melons	0	1.12	0.87	23	30
						3	0.55	0.24	48	110
						7	0.21	NA	120	NA
Blueberries	1.5	1.5	5,000	Hand harvesting, pruning, thinning	Melons	0	1.68	1.3	12	16
						5	0.51	0.15	41	140
						9	0.20	NA	110	NA
			1,000	Irrigating and scouting	Melons	0	1.68	1.3	62	81
						1	1.33	0.85	79	120
						2	1.05	NA	100	NA
Brussel Sprouts and Cauliflower	1	1	5,000	Topping, irrigating, hand harvesting, and tying	Melons	0	1.12	0.87	19	24
						4	0.43	0.16	48	130
						8	0.17	NA	120	NA
			4,000	Irrigating and scouting	Melons	0	1.12	0.87	23	30
						3	0.55	0.24	48	110
						7	0.21	NA	120	NA

Table 20. Short-Term Occupational Post-Application Exposures to Endosulfan: Associated Margins of Safety (Continued)

Crop ^a	Maximum Label Application Rate (lb. a.i./acre) ^d		Transfer Coefficient (cm ² /hr) ^e	Work Activity ^f	Surrogate Crop for DFR Data ^g	DAT ^h	DFR _a (µg/cm ²) ⁱ		MOE ^j	
	WP ^b	EC ^c					WP	EC	WP	EC
Sweet Corn	1.5	1.5	17,000	Detasseling	Melons	0	1.68	1.30	4	5
						14	0.077	0.059	80	100
						19	0.060	NA	100	NA
			1,000	Irrigating and scouting	Melons	0	1.68	1.30	62	81
						1	1.33	0.85	79	120
						2	1.05	NA	100	NA
Cucumber, Melons, Pumpkin, Squash, Beans, Celery, Lettuce, Spinach, Carrots, White Potatoes	1	1	2,500	Hand harvesting, pruning, thinning, turning, and leaf pulling	Melons	0	1.12	0.87	37	49
						2	0.70	0.37	60	110
						5	0.34	NA	120	NA
			1,500	Irrigating and scouting	Melons	0	1.12	0.87	62	81
						1	0.89	0.57	79	120
						2	0.70	NA	100	NA
Carrots	1	1	300	Irrigating and scouting	Melons	0	1.12	0.87	310	400
Pepper, Eggplant, Tomato	1	1	1,000	Hand harvesting, staking, tying, pruning, thinning, and training	Melons	0	1.12	0.87	94	120
						1	0.89	NA	120	NA
			700	Irrigating and scouting	Melons	0	1.12	0.87	130	170
Pineapple	2	2	1,000	Hand harvesting	Melons	0	2.24	1.73	47	60
						2	1.40	0.74	75	140
						4	0.87	NA	120	NA
			500	Irrigating and scouting	Melons	0	2.25	1.73	94	120
						1	1.77	NA	120	NA

Table 20. Short-Term Occupational Post-Application Exposures to Endosulfan: Associated Margins of Safety (Continued)

Crop ^a	Maximum Label Application Rate (lb. a.i./acre) ^d		Transfer Coefficient (cm ² /hr) ^e	Work Activity ^f	Surrogate Crop for DFR Data ^g	DAT ^h	DFR _a (µg/cm ²) ⁱ		MOE ^j	
	WP ^b	EC ^c					WP	EC	WP	EC
Strawberry	2	2	1,500	Hand harvesting, pinching, pruning, and training.	Melons	0	2.24	1.73	31	40
						3	1.10	0.48	64	140
						5	0.69	NA	100	NA
			400	Irrigating and scouting	Melons	0	2.24	1.73	120	150
Collard Greens, Kale, Mustard Greens (edible crop)	1	1	2,500	Hand harvesting, pruning, and thinning	Melons	0	1.12	0.87	37	49
						2	0.7	0.37	60	110
						5	0.34	NA	120	NA
			1,500	Irrigating and scouting	Melons	0	1.12	0.87	62	81
						1	0.89	0.57	79	120
						2	0.7	NA	100	NA
Radish, Rutabaga, and Turnip (seed crop only)	2	2	300	Irrigating and scouting	Melons	0	2.24	1.73	160	200
Kohlrabi, Broccoli, Cabbage (seed crop)	2	2	4,000	Irrigating and scouting	Melons	0	2.25	1.73	12	15
						5	0.69	0.21	38	130
						10	0.21	NA	130	NA
Tobacco	1.5	1	2,000	Hand harvesting, pruning, striping, thinning, topping, and hand weeding	Melons	0	1.68	0.87	31	61
						2	1.05	0.37	50	140
						5	0.51	NA	100	NA
			1,300	Irrigating and scouting	Melons	0	1.68	0.87	48	93
						1	1.33	0.57	61	140
						4	0.65	NA	120	NA

Table 20. Short-Term Occupational Post-Application Exposures to Endosulfan: Associated Margins of Safety (Continued)

Crop ^a	Maximum Label Application Rate (lb. a.i./acre) ^d		Transfer Coefficient (cm ² /hr) ^e	Work Activity ^f	Surrogate Crop for DFR Data ^g	DAT ^h	DFR _a (µg/cm ²) ⁱ		MOE ^j	
	WP ^b	EC ^c					WP	EC	WP	EC
Collard Greens, Kale, Mustard Greens (seed crop only)	2	2	1,500	Irrigating and scouting	Melons	0	2.24	1.73	31	40
						3	1.10	0.48	64	140
						5	0.69	NA	100	NA
Sweet Potatoes	2	2	2,500	Hand harvesting, pruning, thinning	Melons	0	2.24	1.73	19	24
						4	0.87	0.32	48	130
						8	0.34	NA	130	NA
			1,500	Irrigating and scouting	Melons	0	2.24	1.73	31	40
						3	1.1	0.48	64	140
						5	0.69	NA	100	NA
Cotton	1.5	1.5	2,500	Hand harvesting, pruning, thinning	Melons	0	1.68	1.3	25	32
						3	0.83	0.36	51	120
						6	0.41	NA	100	NA
			1,500	Irrigating and scouting	Melons	0	1.68	1.3	42	54
						2	1.05	0.55	67	130
						4	0.65	NA	110	NA

Endnotes:

NA = Not applicable (i.e., MOE >100 on a previous day, or formulation use not relevant for the particular crop).

^a Crops were grouped according to similar application rates, transfer coefficients, and surrogate DFR data sources.

^b WP = wettable powder formulation.

^c EC = emulsifiable concentrate formulation.

^d Maximum application rates as stated on the current labels for Phaser[®] 50WSB, Phaser[®] 3EC, and Thiodan[®] 50WP formulations.

^e Transfer coefficients from the Sciences Advisory Council on Exposure Policy 3.1 (USEPA 2000a).

^f Work activities from Sciences Advisory Council on Exposure Policy 3.1 (USEPA 2000a); some activities listed may not occur for every crop in the grouping.

^g The appropriate DFR surrogate data source for each crop was determined by the similarity in crop types and quality of the data.

^h DAT = Days after treatment, where Day 0 = 12 hours after treatment.

ⁱ Predicted DFR values were obtained by fitting biphasic regression curves to the study data of endosulfan on the foliage of melons, peaches, and grapes in California (MRID 444031-02); if necessary, predicted DFR values were adjusted proportionally to reflect differences in application rate between the study and the maximum label rate for the WP and EC formulations.

^j MOE = [NOEL (mg/kg/day)]/[Dermal Dose (mg/kg/day)], where the dermal NOEL = 12 mg/kg/day, and the target MOE is 100.

E. ESTIMATION OF INTERMEDIATE-TERM POST-APPLICATION WORKER EXPOSURES TO ENDOSULFAN

Because endosulfan is registered for a large number of crops, sometimes involving multiple applications, there is potential for post-application workers to receive repeated exposures during reentering of treated growing areas to conduct various work activities, such as thinning, pruning, scouting, irrigating and hand harvesting. The anticipated duration for intermediate-term exposures may be from 30 days to several months. During this time, workers are likely to travel from field to field. In the case of short-term exposures, which were addressed previously, the worker is assumed to contact the residue level that occurs on the day that the calculated MOE reaches or exceeds the target MOE. In contrast, for intermediate post-application exposures, it is unlikely that any given reentry worker would contact the same residue level every day. A reasonable yet conservative approach would be to assume that the worker would be exposed to the average of the residue values that are possible within 30 days after the target MOE is reached. It is the position of the ETF that the most appropriate target MOE for intermediate-term post-application occupational exposures to endosulfan is 100. The ETF believes that the extra 3-fold factor applied by the Agency to obtain a target MOE of 300 is not appropriate, for reasons previously stated (see Section III).

(1) *Assumptions.* A number of assumptions were made in conducting the intermediate-term post-application worker exposure and risk assessment. These include:

- The maximum transfer coefficient for each crop category per USEPA HED Policy Memo No. 3.1 (USEPA 2000a), which utilizes the ARTF database;
- 30-Day average of daily post-application DFR values based on biphasic dissipation kinetics from the first day the exposure yields an MOE of 100 to 30 days later;
- National average crop-specific use rates when available (AgrEvo 1999; USEPA 2000d), or maximum label rates when an average value is not available;
- Exposure duration is assumed to be 8 hours per day, representing a work day;
- An average body weight of 70 kg; and
- A dermal NOAEL of 12 mg/kg/day based is the most appropriate toxicological benchmark.

(2) Exposure calculations. The predicted DFR value (DFR_p) on each day post-application derived from the biphasic regression equations were adjusted to reflect actual average crop-specific application rates or crop-specific label maximum use rates for the WP and EC formulations, using the following equation:

$$DFR_a(\mu\text{g}/\text{cm}^2) = \frac{\text{Study DFR}_p(\mu\text{g}/\text{cm}^2) \times \text{Crop-Specific Application Rate (lb a.i./acre)}}{\text{Study Application Rate (lb a.i./acre)}}$$

The adjusted residue data from the two phases of dissipation were merged, whereby, for the WP formulation, Days 0 through 10 were represented by the Phase 1 regression curve and Days 11 and beyond were represented by the Phase 2 regression curve; and for the EC formulation, Days 0 through 7 were represented by the Phase 1 regression curve and Days 8 and beyond were represented by the Phase 2 regression curve.

Intermediate-term daily doses were calculated as follows based on the formulation-specific regression equations obtained considering the biphasic nature of the DFR dissipation curves.

$$ADD = [DFR_a \times TC \times ET \times (\text{mg}/1,000 \mu\text{g})]/BW$$

where,

ADD	=	per-event average daily dose (mg/kg/day)
DFR _a	=	adjusted dislodgeable foliar residue value (μg/cm ²)
TC	=	transfer coefficient for specific work activity (cm ² /hr)
ET	=	exposure duration (8 hr/day)
BW	=	body weight (70 kg).

The estimated intermediate-term exposures on key days of reentry are shown in Table 21.

(3) Calculation of intermediate-term post-application risks. The Margins-of-Exposure (MOEs) are calculated based on the estimated exposures per the 30-day average DFR values based on the biphasic dissipation regression equations. The equation for calculation of the MOE is as follows:

$$MOE = NOAEL/ADD$$

where,

MOE	=	margin of exposure (unitless)
NOAEL	=	No-Observed-Adverse-Effect-Level
ADD	=	average daily dose (mg/kg/day)

For assessment of intermediate-term post-application worker risks, the target MOE is 100 and the NOAEL is 12 mg/kg/day based on the available dermal exposure studies described previously. The results of the MOE estimation are shown in Table 21.

Table 21. Intermediate-Term Occupational Post-Application Exposures to Endosulfan: Associated Margins of Safety

Crop ^a	Transfer Coefficient (cm ² /hr) ^b	Work Activity ^c	DFR Surrogate Data Source ^d	Formulation Type ^e	Application Rate ^f (lbs a.i./acre)	Decline Period ^g (DAT) ^h	Average DFR (μg/cm ²) ⁱ	MOE ^j
Table Grapes/Raisins	10,000	Cane turning and tying, girdling	Grapes	WP	1.0 (average)	27 to 57	0.05273	200
				EC		4 to 34	0.02013	520
Juice Grapes	5,000	Tying, training, hand harvesting, hand pruning, thinning	Grapes	WP	1.0 (average)	8 to 38	0.1258	170
				EC		2 to 32	0.02800	750
Grapes (Table/Raisin and Juice)	1,000	Scouting and irrigating	Grapes	WP	1.0 (average)	1 to 31	0.2110	500
				EC		1 to 31	0.03542	3,000
Cherry, Pear, Plum, Prune	8,000	Thinning, staking, topping, training, hand harvesting	Peaches	WP	1.8 (average)	8 to 38	0.04751	280
				EC		2 to 32	0.02255	580
	1,000	Irrigating and scouting	Peaches	WP		1 to 31	0.09967	1,100
				EC		1 to 31	0.02659	3,900
Apples	8,000	Thinning, staking, topping, training, hand harvesting	Peaches	WP	1.1 (average)	5 to 35	0.03809	340
				EC		1 to 31	0.01625	810
	1,000	Irrigating and scouting	Peaches	WP		1 to 31	0.06090	1,700
				EC		1 to 31	0.01625	6,500
Ornamental Trees/Shrubs, Including Evergreen Trees and Non-Bearing Citrus	3,000	Hand pruning and seed cone harvesting	Peaches	WP	3.0 (max.)	5 to 35	0.1039	340
				EC		1 to 31	0.04431	790
	1,000	Irrigating and scouting	Peaches	WP		1 to 31	0.1661	630
				EC		1 to 31	0.04431	2,400
Macadamia Nuts	2,500	Hand harvesting, pruning, thinning	Peaches	WP	3.0 (max.)	4 to 34	0.1156	360
				EC		1 to 31	0.04431	950
	500	Irrigating and scouting	Peaches	WP		1 to 31	0.1661	1,300
				EC		1 to 31	0.04431	4,700

Table 21. Intermediate-Term Occupational Post-Application Exposures to Endosulfan: Associated Margins of Safety (Continued)

Crop ^a	Transfer Coefficient (cm ² /hr) ^b	Work Activity ^c	Surrogate Crop for DFR Data ^d	Formulation Type ^e	Application Rate ^f (lbs a.i./acre)	Decline Period ^g (DAT) ^h	Average DFR (µg/cm ²) ⁱ	MOE ^j
Almonds	2,500	Hand harvesting, pruning	Peaches	WP	2.0 (max.)	2 to 32	0.09746	430
				EC		1 to 31	0.02954	1,400
	500	Irrigating and scouting	Peaches	WP		1 to 31	0.1107	1,900
				EC		1 to 31	0.02954	7,100
Peaches	8,000	Thinning, staking, topping, training, hand harvesting	Peaches	WP	0.7 (average)	2 to 32	0.03411	380
				EC		1 to 31	0.01034	1,300
	1,000	Irrigating and scouting	Peaches	WP		1 to 31	0.03876	2,700
				EC		1 to 31	0.01034	10,000
Apricots and Nectarines	8,000	Thinning, staking, topping, training, hand harvesting	Peaches	WP	0.84 (average)	3 to 33	0.03626	360
				EC		1 to 31	0.01241	1,100
	1,000	Irrigating and scouting	Peaches	WP		1 to 31	0.04651	2,300
				EC		1 to 31	0.01241	8,500
Pecans	2,500	Hand harvesting, pruning, thinning	Peaches	WP	0.62 (average)	1 to 31	0.03433	1,200
				EC		1 to 31	0.009156	4,600
	500	Irrigating and thinning	Peaches	WP		1 to 31	0.03443	6,100
				EC		1 to 31	0.009156	23,000
Hazelnuts and Walnuts	2,500	Hand harvesting and pruning	Peaches	WP	1.0 (average) ^k	1 to 31	0.05508	760
				EC		1 to 31	0.01477	2,800
	500	Irrigating and scouting	Peaches	WP		1 to 31	0.05508	3,800
				EC		1 to 31	0.01477	14,000

Table 21. Intermediate-Term Occupational Post-Application Exposures to Endosulfan: Associated Margins of Safety (Continued)

Crop ^a	Transfer Coefficient (cm ² /hr) ^b	Work Activity ^c	Surrogate Crop for DFR Data ^d	Formulation Type ^e	Application Rate ^f (lbs a.i./acre)	Decline Period ^g (DAT) ^h	Average DFR (µg/cm ²) ⁱ	MOE ^j
Cabbage and Cauliflower	5,000	Hand harvesting, pruning, and thinning	Melons	WP	0.66 (average) ^l	6 to 36	0.03797	550
				EC		3 to 33	0.02936	720
	4,000	Irrigating and scouting	Melons	WP		5 to 35	0.04489	580
				EC		2 to 32	0.03697	710
Kohlrabi (seed crop only)	5,000	Thinning	Melons	WP	2.0 (max.)	10 to 40	0.06850	310
				EC		5 to 35	0.06463	320
	4,000	Irrigating and scouting	Melons	WP		10 to 40	0.06850	380
				EC		5 to 35	0.06463	410
Blueberries	5,000	Hand harvesting, pruning, thinning	Melons	WP	0.52 (average)	5 to 35	0.03537	590
				EC		2 to 32	0.02913	720
	1,000	Irrigating and scouting	Melons	WP		1 to 31	0.07714	1,400
				EC		1 to 31	0.0384	2,700
Clover	1,500	Irrigating and scouting	Melons	WP	0.5 (max.)	1 to 31	0.07418	940
				EC		1 to 31	0.03700	1,900
Oats and Rye	1,500	Irrigating and scouting	Melons	WP	0.6 (average)	1 to 31	0.08900	790
				EC		1 to 31	0.04431	1,600
Brussel Sprouts and Broccoli (edible crop)	5,000	Topping, hand harvesting, and tying	Melons	WP	0.8 (average)	7 to 37	0.03948	530
				EC		3 to 33	0.03559	590
	4,000	Irrigating and scouting	Melons	WP		6 to 36	0.04602	570
				EC		3 to 33	0.03559	740

Table 21. Intermediate-Term Occupational Post-Application Exposures to Endosulfan: Associated Margins of Safety (Continued)

Crop ^a	Transfer Coefficient (cm ² /hr) ^b	Work Activity ^c	Surrogate Crop for DFR Data ^d	Formulation Type ^e	Application Rate ^f (lbs a.i./acre)	Decline Period ^g (DAT) ^h	Average DFR (µg/cm ²) ⁱ	MOE ^j
Beans, Celery, Spinach	2,500	Hand harvesting, pruning, thinning, turning, and leaf pulling	Melons	WP	0.6 (average) ^m	2 to 32	0.07228	580
				EC		1 to 31	0.04431	950
	1,500	Irrigating and scouting	Melons	WP		1 to 31	0.08900	790
				EC		1 to 31	0.04431	1,600
Pumpkins, Squash, Cantaloupe	2,500	Hand harvesting, pruning, thinning, turning, and leaf pulling	Melons	WP	1.0 (max.)	5 to 35	0.06802	620
				EC		2 to 32	0.05602	750
	1,500	Irrigating and scouting	Melons	WP		2 to 32	0.1205	580
				EC		1 to 31	0.07385	950
Lettuce, Honeydew Melons	2,500	Hand harvesting, pruning, thinning, turning, and leaf pulling	Melons	WP	0.7 (average) ⁿ	3 to 33	0.06901	610
				EC		1 to 31	0.05169	810
	1,500	Irrigating and scouting	Melons	WP		1 to 31	0.1038	670
				EC		1 to 31	0.05169	1,400
Barley	1,500	Irrigating and scouting	Melons	WP	0.33 (average)	1 to 31	0.04895	1,400
				EC		1 to 31	0.02437	2,900
Wheat	1,500	Irrigating and scouting	Melons	WP	0.39 (average)	1 to 31	0.05785	1,200
				EC		1 to 31	0.0288	2,400
Cucumbers	2,500	Hand harvesting, pruning, thinning, turning, and leaf pulling	Melons	WP	0.83 (average)	4 to 34	0.0676	620
				EC		2 to 32	0.04649	900
	1,500	Irrigating and scouting	Melons	WP		2 to 32	0.09998	700
				EC		1 to 31	0.06129	1,100

Table 21. Intermediate-Term Occupational Post-Application Exposures to Endosulfan: Associated Margins of Safety (Continued)

Crop ^a	Transfer Coefficient (cm ² /hr) ^b	Work Activity ^c	Surrogate Crop for DFR Data ^d	Formulation Type ^e	Application Rate ^f (lbs a.i./acre)	Decline Period ^g (DAT) ^h	Average DFR (µg/cm ²) ⁱ	MOE ^j
Sweet Corn	17,000	Detasseling	Melons	WP	0.7 (average)	11 to 41	0.02192	280
				EC		6 to 36	0.02052	300
	1,000	Irrigating and scouting	Melons	WP		1 to 31	0.1038	1,000
				EC		1 to 31	0.05169	2,000
Watermelons	2,500	Hand harvesting, pruning, thinning, turning, and leaf pulling	Melons	WP	1.0 (average)	5 to 35	0.06802	620
				EC		2 to 32	0.05602	750
	1,500	Irrigating and scouting	Melons	WP		2 to 32	0.1205	580
				EC		1 to 31	0.07385	950
White Potatoes	2,500	Hand harvesting, pruning, thinning, turning, and leaf pulling	Melons	WP	0.8 (average)	4 to 34	0.06515	640
				EC		2 to 32	0.04482	940
	1,500	Irrigating and scouting	Melons	WP		2 to 32	0.09637	730
				EC		1 to 31	0.05915	1,200
Pepper, Eggplant	1,000	Hand harvesting, staking, tying, pruning, thinning, and training	Melons	WP	0.6 (average) ^o	1 to 31	0.08900	1,200
				EC		1 to 31	0.04431	2,400
	700	Irrigating and scouting	Melons	WP		1 to 31	0.08900	1,700
				EC		1 to 31	0.04431	3,400
Pineapple	1,000	Hand harvesting	Melons	WP	2.0 (max.)	4 to 34	0.1629	640
				EC		2 to 32	0.1120	940
	500	Irrigating and scouting	Melons	WP		1 to 31	0.2967	710
				EC		1 to 31	0.1477	1,400

Table 21. Intermediate-Term Occupational Post-Application Exposures to Endosulfan: Associated Margins of Safety (Continued)

Crop ^a	Transfer Coefficient (cm ² /hr) ^b	Work Activity ^c	Surrogate Crop for DFR Data ^d	Formulation Type ^e	Application Rate ^f (lbs a.i./acre)	Decline Period ^g (DAT) ^h	Average DFR (µg/cm ²) ⁱ	MOE ^j
Strawberry	1,500	Hand harvesting, pinching, pruning, and training.	Melons	WP	0.92 (average)	2 to 32	0.1108	630
				EC		1 to 31	0.06794	1,000
	400	Irrigating and scouting	Melons	WP		1 to 31	0.1365	1,900
				EC		1 to 31	0.06794	3,900
Carrots	2,500	Hand harvesting, pruning, thinning	Melons	WP	0.56 (average)	2 to 32	0.06746	620
				EC		1 to 31	0.04135	1,000
	300	Irrigating and scouting	Melons	WP		1 to 31	0.08307	4,200
				EC		1 to 31	0.04135	8,500
Collard Greens, Kale, Mustard Greens (edible crop)	2,500	Hand harvesting, pruning, and thinning	Melons	WP	1.0 (max.)	5 to 35	0.06802	620
				EC		2 to 32	0.05602	750
	1,500	Irrigating and scouting	Melons	WP	1.0 (max.)	2 to 32	0.1205	350
				EC		1 to 31	0.07385	950
Radish, Rutabaga, and Turnip (seed crop only)	300	Irrigating and scouting	Melons	WP	2.0 (max.)	1 to 31	0.2967	1,200
				EC		1 to 31	0.1477	2,400
Collard Greens, Kale, Mustard Greens (seed crop only)	1,500	Irrigating and scouting	Melons	WP	2.0 (max.)	5 to 35	0.1360	510
				EC		3 to 33	0.08897	790
Tomato	1,000	Hand harvesting, staking, tying, pruning, thinning, and training	Melons	WP	0.5 (average)	1 to 31	0.07418	1,400
				EC		1 to 31	0.03693	2,800
	700	Irrigating and scouting	Melons	WP		1 to 31	0.07418	2,000
				EC		1 to 31	0.03693	4,100

Table 21. Intermediate-Term Occupational Post-Application Exposures to Endosulfan: Associated Margins of Safety (Continued)

Crop ^a	Transfer Coefficient (cm ² /hr) ^b	Work Activity ^c	Surrogate Crop for DFR Data ^d	Formulation Type ^e	Application Rate ^f (lbs a.i./acre)	Decline Period ^g (DAT) ^h	Average DFR (μg/cm ²) ⁱ	MOE ^j
Sweet Potatoes	2,500	Hand harvesting, pruning, thinning	Melons	WP	0.5 (average)	2 to 32	0.06023	700
				EC		1 to 31	0.03692	1,100
	1,500	Irrigating and scouting	Melons	WP		1 to 31	0.07417	940
				EC		1 to 31	0.03692	1,900
Tobacco	2,000	Hand harvesting, pruning, striping, thinning, topping, and hand weeding	Melons	WP	0.9 (average)	3 to 33	0.08873	590
				EC		1 to 31	0.06646	790
	1,300	Irrigating and scouting	Melons	WP		1 to 31	0.1335	610
				EC		1 to 31	0.06646	1,200
Cotton	2,500	Hand harvesting, pruning, thinning	Melons	WP	0.4 (average)	1 to 31	0.05933	710
				EC		1 to 31	0.02954	1,400
	1,500	Irrigating and scouting	Melons	WP		1 to 31	0.05933	1,200
				EC		1 to 31	0.02954	2,400

Endnotes:

^a Crops were grouped according to similar application rates, transfer coefficients, and surrogate DFR data sources.

^b Transfer coefficients from the Sciences Advisory Council on Exposure Policy 3.1 (USEPA 2000a).

^c Work activities from Sciences Advisory Council on Exposure Policy 3.1 (USEPA 2000a); some activities listed may not occur for every crop in the grouping.

^d The appropriate DFR surrogate data source for each crop was determined by the similarity in crop types and quality of the data.

^e WP = wettable powder formulation; EC = emulsifiable concentrate formulation.

^f Average crop-specific application rates where available; where no average data are available, the maximum crop-specific application rate as stated on the current endosulfan labels is used.

^g Period of time over which the predicted residues were average for 30 days, starting with the first day of decline in which the estimated MOE exceeds 100.

^h DAT = Days after treatment, where 0 days = 12 hours after treatment.

ⁱ Predicted DFR values were obtained through endosulfan residue data on the foliage of melons, peach trees, and grapes in California [MRID No. 444031-02] based on biphasic dissipation regression curves; residues values at each day post-application were adjusted proportionally to reflect crop-specific application rates as follows: Adjusted DFR = [(Study DFR) x (Crop Application Rate)] / [Study Application Rate].

^j MOE = [NOAEL (mg/kg/day)] / [Dermal Dose (mg/kg/day)], where the dermal NOEL = 12 mg/kg/day, and the target MOE is 100.

^k The average use rate for hazelnuts is 1 lb a.i./acre; the average use rate for walnuts is 0.9 lb a.i./acre, which is rounded to 1.0 lb a.i./acre for this assessment.

^l The average use rate for cauliflower is 0.66 lb a.i./acre; the average use rate for cabbage is 0.65 lb a.i./acre, which is approximated as 0.66 lb a.i./acre for this assessment.

^m The average use rate is 0.6 lb a.i./acre for beans; the use rates for celery and spinach are 0.62 lb a.i./acre and 0.64 lb a.i./acre, respectively, which are rounded to 0.6 lb a.i./acre.

ⁿ The average use rate for honeydew melons is 0.7 lb a.i./acre; the average use rate for lettuce is 0.72 lb a.i./acre, which is rounded to 0.7 lb a.i./acre for this assessment.

^o The average use rates for eggplant and peppers are 0.53 lb a.i./acre and 0.63 lb a.i./acre, respectively; these rates are rounded to 0.6 lb a.i./acre for this assessment.

F. Occupational Post-Application Summary

(1) Short-term occupational post-application exposures to endosulfan. The results of the short-term exposure/risk assessment can be summarized in terms of the post-application day at which the reentry interval occurs based on an MOE of 100. For cases where the target MOE is achieved on the day of application (i.e., Day 0), the REI defaults to 24 hours (i.e. 1 day) based on label statements. These results are summarized in Table 22. See Table 20 for a more detailed summary of short-term occupational post-application exposures and associated MOEs.

For the emulsifiable concentrate (EC) formulation, the calculated MOE equals or exceeds the target MOE of 100 on Day 0 or Day 1 for 21 of the 41 crop/work activity combinations. For the EC formulation, 5 of the 41 crop/work activity combinations are associated with an REI of 2 days, 8 of the 41 crop/work activity combinations are associated with an REI of 3 days, 4 are associated with an REI of 4 days, and 3 are associated with an REI greater than or equal to 5 days.

For the wettable powder (WP) formulation, the calculated MOE equals or exceeds the target MOE of 100 on Day 0 or Day 1 for 12 of the 41 crop/work activity combinations. For the WP formulation, 6 of the 41 crop/work activity combinations are associated with an REI of 2 days, none of the 41 crop/work activity combinations are associated with an REI of 3 days, and 4 are associated with an REI of 4 days. Nineteen of the crop/work activity combinations are associated with an REI greater than or equal to 5 days. Seven of the crop/work activity combinations for the WP formulation are associated with an REI greater than 1 week (7 days), including selected activities for tables grapes, juice and raisin grapes, apples, apricots, cherry, plum, peach, nectarine, pear, prune, and sweet corn.

(2) Intermediate-term occupational post-application exposures to endosulfan. As must be the case, all of the crop/work activity for both the WP and EC formulations, all of the intermediate-term occupational post-application exposures to endosulfan are associated with the target MOEs of 100 or greater. Furthermore, for the EC formulation, all of the intermediate-term post-application exposures are associated with MOEs that exceed the Agency's target MOE of 300, except for that associated with the detasseling of corn (MOE = 230). For the WP formulations, the only intermediate-term post-application exposures that exceed the Agency's target MOE of 300 are (1) cane turning, tying, and girdling of table grapes (MOE = 200); (2) tying, training, hand harvesting, hand pruning, and thinning of juice grapes (MOE = 170); (3) thinning, staking, topping, training, and hand harvesting of cherries, pears, and plums/prunes (280); and (4) detasseling of sweet corn (MOE = 280). As noted previously, it is the position of the ETF that the most appropriate target MOE for assessing intermediate-term post-application occupational exposures to endosulfan is 100. See Table 21 for a summary of intermediate-term post-application occupational exposures and associated MOEs.

Table 22. Estimated Reentry Intervals for Endosulfan^a

Crop ^b	Work Activity	DAT (days) ^c	
		WP ^d	EC ^e
Table Grapes, Raisins	Cane turning, tying, girdling	35	4
Juice Grapes	Tying, turning, hand harvesting, hand pruning, thinning	10	3
Grapes (Table/Raisins/Juice)	Irrigating and scouting	2	0
Apple, Apricot, Cherry, Plum, Peach, Nectarine, Pear, Prune	Thinning, staking, topping, training, hand harvesting	10	3
	Irrigating and scouting	0	0
Ornamental Trees/Shrubs	Hand pruning, seed cone harvesting	5	0
	Irrigating and scouting	0	0
Macadamia Nuts/Pecans	Hand harvesting, pruning, thinning	4	0
	Irrigating and scouting	0	0
Alfalfa, Clover	Irrigating and scouting	0	0
Small Grains	Irrigating and scouting	1	0
Hazelnuts, Almonds, Pecans	Hand harvesting, pruning	2	0
	Irrigating and scouting	0	0
Blueberries	Hand harvesting, pruning, thinning	9	5
	Irrigating and scouting	2	0
Broccoli, Cabbage (edible crop)	Hand harvesting, pruning, thinning	8	4
	Irrigating and scouting	7	3
Brussel Sprouts, Cauliflower	Topping, hand harvesting, tying	8	4
	Irrigating and scouting	7	3
Sweet Corn	Detasseling	19	14
	Irrigating and scouting	2	1
Cucumbers, Melons, Pumpkin, Squash, Beans, Peas, Celery, Lettuce, Spinach, Carrots, Potato	Hand harvesting, pruning, thinning, turning, leaf pulling	5	2
	Irrigating and scouting	2	1
Carrots	Irrigating and scouting	0	0
Pepper, Eggplant, Tomato	Hand harvesting, staking, tying, pruning, thinning, training	1	0
	Irrigating and scouting	0	0

Table 22. Estimated Reentry Intervals for Endosulfan^a (Continued)

Crop ^b	Work Activity	DAT (days) ^c	
		WP ^d	EC ^e
Pineapple	Hand harvesting	4	2

	Irrigating and scouting	1	0
Strawberry	Hand harvesting, pinching, pruning, training	5	3
	Irrigating and scouting	0	0
Collard Greens, Kale, Mustard Greens (edible crop)	Hand harvesting, pruning, thinning	5	2
	Irrigating and scouting	2	1
Radish, Rutabaga, Turnip (seed crop only)	Irrigating and scouting	0	0
Kohlrabi, Broccoli, Cabbage (seed crop)	Irrigating and scouting	10	5
Collard Greens, Kale, Mustard Greens (seed crop)	Irrigating and scouting	5	3
Tobacco	Hand harvesting, pruning, striping, thinning, topping, hand weeding	5	2
	Irrigating and scouting	4	1
Sweet Potato	Hand harvesting, pruning, thinning	8	4
	Irrigating and scouting	5	3
Cotton	Hand harvesting, pruning, thinning	6	3
	Irrigating and scouting	4	2

^a Assuming biphasic kinetics, formulation-specific DFR data, adjustment of DFR data to reflect actual application rates, ARTF transfer coefficients from the Science Advisory Council on Exposure Policy 3.1 (USEPA 2000a), and a dermal NOEL of 12 mg/kg/day.

^b Crops were grouped according to similar application rates, transfer coefficients and surrogate DFR data sources.

^c DAT = Days after treatment; REI is day on which MOE first equals or exceeds 100; if Day 0, REI defaults to 1 day.

^d WP = Wettable powder formulation.

^e EC = Emulsifiable concentrate formulation.

VIII. DISCUSSION

This document has provided an alternative assessment of formulation-specific worker exposures for mixing/loading, applying, flagging, and reentry activities associated with the use of endosulfan. The handler exposure assessment was conducted using an approach similar to that used by the Agency in its revised occupational exposure assessment (USEPA 2001a), and using the same data from the Pesticide Handlers Exposure Database, as presented in the surrogate exposure guide (USEPA 1998a). Because the ETF believes that the use of label-recommended protective headgear must be accounted for, the Task Force has assigned a default value of 50 percent to protected areas (i.e., head and neck). While the Agency has shown reluctance in the past to assign a specific value for protective headgear, the Task Force encourages the Agency to adopt the 50 percent value as being generally consistent with other dermal protection factors used by the Agency (e.g., for a single layer of clothing), and as being sufficiently conservative. The ETF also urges the Agency to consider harmonizing its assumption for acres treated per day for aerial treatment of small grains, cotton, corn, and clover to be consistent with the 600 acres per day assumed by the California Department of Pesticide regulation (DPR), Worker Health and Safety Branch. The value of 1,200 acres/day for aerial treatment of these crops, as assumed by the Agency in its revised occupational assessment (USEPA 2001a), appears to be an extreme “high-end” value. Furthermore, the Task Force urges the Agency to consider harmonizing its protection factors for normal and protective clothing to be more consistent with the California DPR. The current dermal protection factors for normal and protective clothing used by the Agency’s revised occupational exposure assessment (USEPA 2001a), and reflected in this current assessment (with the exception of the 50 percent exposure reduction factor for protective headgear) are a significant source of over-conservatism and should be reconsidered. Additionally, the available data on the dermal penetration of endosulfan through human skin versus rat skin would suggest that an adjustment of dermal exposures to account for the reduced permeability of endosulfan in human skin would be warranted (ETF 2001a).

For estimation of post-application occupational exposures, we have proposed consideration of the biphasic kinetics to describe the DFR dissipation data in order to obtain a better predictive model for DFRs for endosulfan specifically. In all cases, the r^2 value for Phase 1 (the critical time range for the great majority of the calculated biphasic DFRs) indicates a better fit to the data than a simple log-linear fit across the entire time frame of DFR dissipation. The REIs estimated in this report are likely to overestimate central tendency reentry intervals, and the MOEs are likely to be underestimated, because (a) some of the transfer coefficient (TC) values represent the upper end of the range of the ARTF values; (b) some of the intermediate-term exposures are based on the maximum application rate, when an average rate is missing; and (c) an adjustment factor for the reduced permeability of human skin to endosulfan relative to dermal permeability in rats was not used.. Thus, these refinements in the post-application occupational reentry exposure assessment, if implemented, would result in lower exposure estimates and higher MOEs for the short-term and intermediate-term post-application worker exposures.

IX. REFERENCES

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ATTACHMENT A

Plots of Endosulfan DFR Dissipation Curves Under Various Kinetics Assumptions

Figure A-1. Regression of Endosulfan Grape DFR on Time for EC Formulation

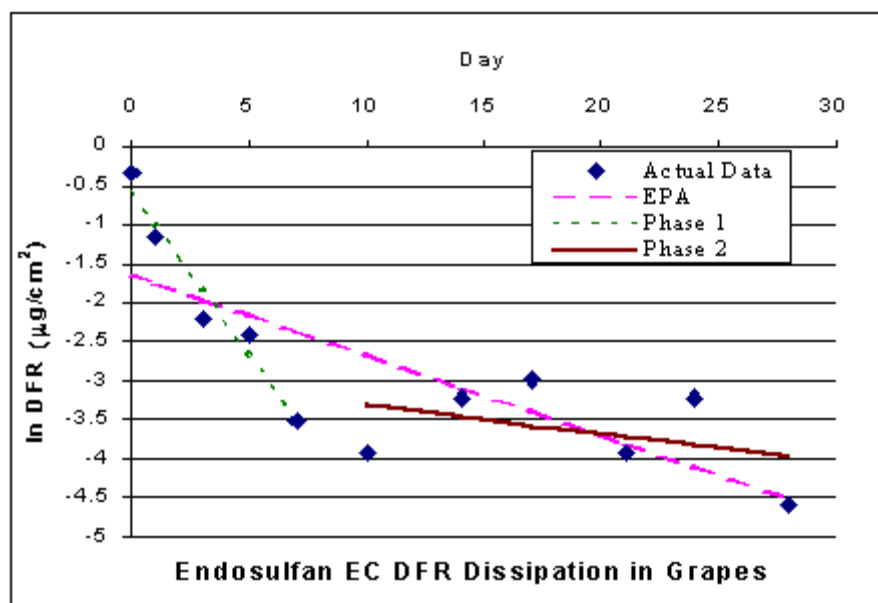


Figure A-2. Regression of Endosulfan Peach DFR on Time for EC Formulation

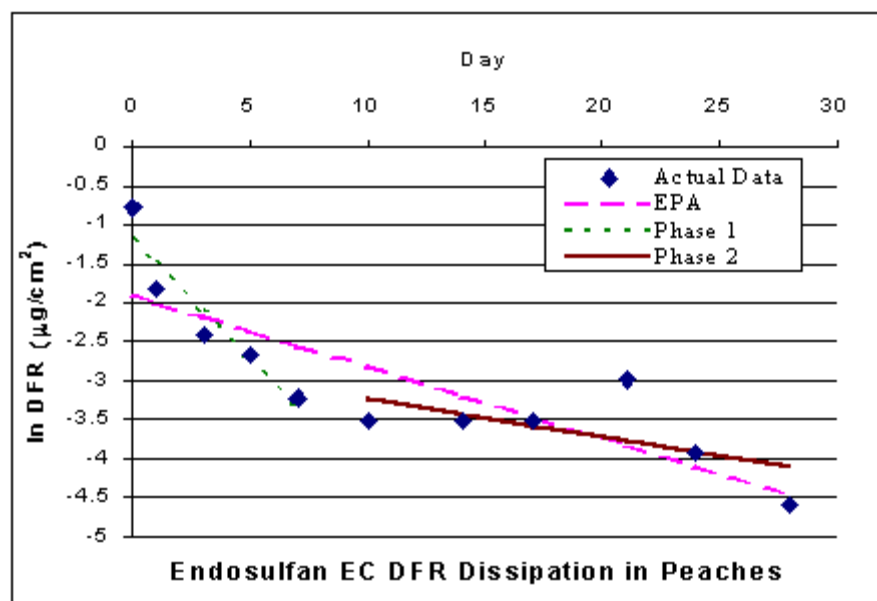


Figure A-3. Regression of Endosulfan Melon DFR on Time for EC Formulation

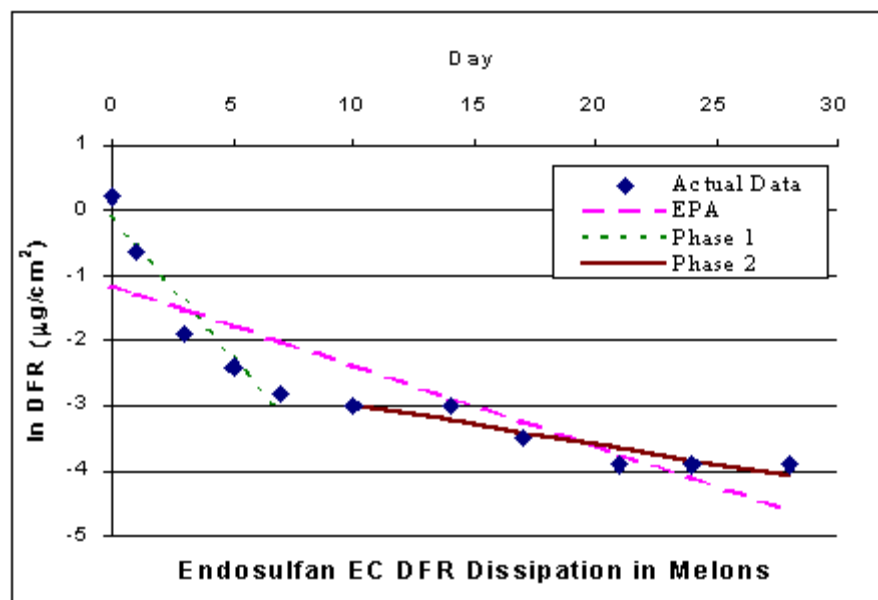


Figure A-4. Regression of Endosulfan Grape DFR on Time for WP Formulation

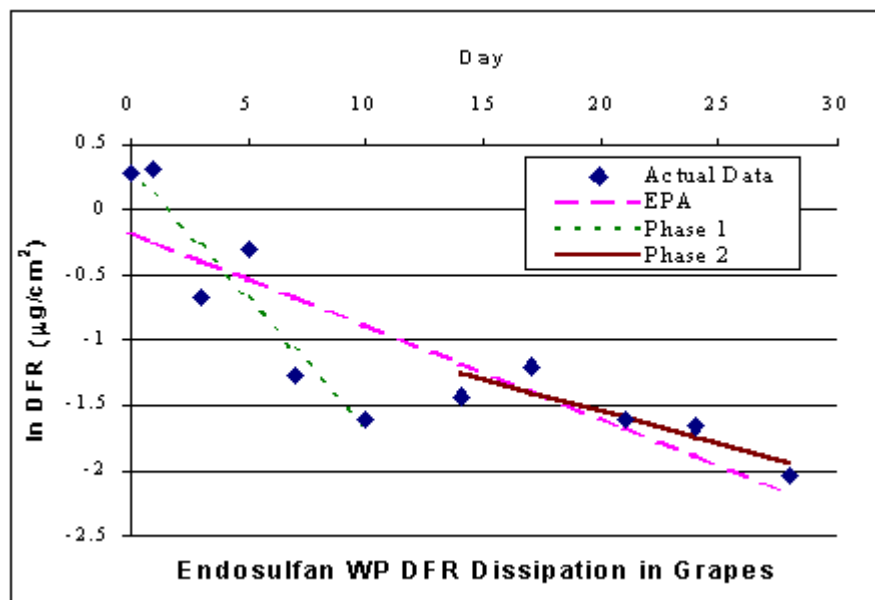


Figure A-5. Regression of Endosulfan Peach DFR on Time for WP Formulation

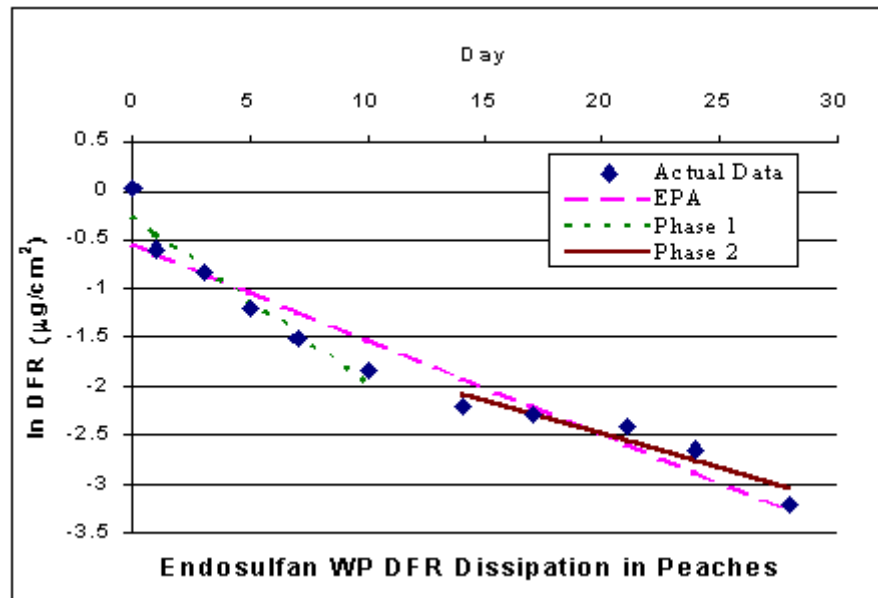


Figure A-6. Regression of Endosulfan Melon DFR on Time for WP Formulation

